

# THE FOOD SAFETY MODERNIZATION ACT’S TESTER AMENDMENT: USEFUL SAFE HARBOR FOR SMALL FARMERS AND FOOD FACILITIES OR WEAK ATTEMPT AT SCALE-APPROPRIATE FARM AND FOOD REGULATIONS?

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I.	Introduction: The U.S. Food Supply, Safest in the World?.....	240
	A. Food Safety History .....	243
	B. Modern Response.....	244
II.	Background on the Food Safety Modernization Act and the Tester Amendment.....	247
	A. FSMA Objectives and Provisions Potentially Affecting Small Farmers and Food Processors.....	247
	B. Produce Safety Standards.....	247
	C. Hazards Analysis and Risk Prevention Controls .....	249
	D. Support for the Tester Amendment.....	251
	E. Opposition to the Tester Amendment .....	254
III.	Weaknesses of the Tester Amendment and FSMA .....	255
	A. Regulatory Burden .....	256
	1. History as a Guide: The Cost of Compliance.....	256
	2. Confusing Language.....	258
	3. Proving the Exemption .....	259
	4. Conflicting Values.....	260
	B. Line Drawing Challenges.....	261
	1. Under-Inclusive and Over-Inclusive .....	261
	2. Polarization of the Playing Field .....	264
	C. Enforcement Challenges .....	265
	1. Lack of Adequate Resources .....	265
	2. Effectiveness of Regulations .....	268

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D.	Taking Options off the Table .....	271
1.	Collaborative Marketing .....	271
2.	Value Added .....	272
E.	Shared Accountability .....	273
F.	Whose Science Do We Use? .....	274
G.	Discretion Provides Uncertainty .....	275
IV.	Alternatives to FSMA Regulatory Approach .....	278
A.	Burden Shifting .....	278
B.	Local Solutions.....	280
C.	Performance Standards.....	282
D.	Consumer Responsibility .....	284
V.	Conclusion .....	285
A.	Does the Food Safety Modernization Act and Included Tester Amendment Serve as a Useful Safe Harbor for Small Farmers or Weak Attempt at Scale-Appropriate Farm and Food Regulations? .....	285
B.	Moving Forward.....	286

## I. INTRODUCTION: THE U.S. FOOD SUPPLY, SAFEST IN THE WORLD?

The U.S. food supply is continually hailed as “among the safest in the world.”<sup>1</sup> Whether that title is deserved or not, an estimated forty-eight million people—or one in six Americans—become infected with a foodborne illness every year, resulting in a yearly average of 128,000 hospitalizations and 3000 deaths.<sup>2</sup> Recent attention and focus on foodborne illness prevalence by government agencies has failed to produce significant reductions in the occurrence of foodborne illness, and in some instances rates continue to climb.<sup>3</sup> Illness out-

1. RENÉE JOHNSON, CONG. RESEARCH SERV., RS 22600, THE FEDERAL FOOD SAFETY SYSTEM: A PRIMER I (2011) [hereinafter JOHNSON, FEDERAL FOOD SAFETY SYSTEM].

2. *Id.*; CDC *Estimates of Foodborne Illness in the United States*, CTRS. FOR DISEASE CONTROL & PREVENTION (Feb. 2011), [http://www.cdc.gov/foodborneburden/PDFs/FACTSHEET\\_A\\_FINDINGS\\_updated4-13.pdf](http://www.cdc.gov/foodborneburden/PDFs/FACTSHEET_A_FINDINGS_updated4-13.pdf). Past estimates ranged even higher. Helena Bottemiller, *New Estimates Lower Incidence of Food Poisoning*, FOOD SAFETY NEWS (Dec. 16, 2010), <http://www.foodsafetynews.com/2010/12/cdc-releases-new-foodborne-illness/> (citing previous data that estimated sixty million illnesses, 325,000 hospitalization, and 5000 deaths each year).

3. *Trends in Foodborne Illness in the United States*, CTRS. FOR DISEASE CONTROL & PREVENTION (Feb. 4, 2013), <http://www.cdc.gov/foodborneburden/trends-in-foodborne-illness.html> (comparing 2011 data with 2006–2008 levels of foodborne illness and examining longer term trends in figure 1); Press Release, Ctrs. for Disease Control & Prevention, No Progress in *Salmo-*

breaks in foods regulated by the U.S. Food and Drug Administration (FDA) have increased from approximately 125 per year in the early 1990s to an average of 300 per year between 1999 and 2006.<sup>4</sup> Total illness outbreaks attributed to all foods have declined since 2006, but incidences of outbreaks remain a pressing concern.<sup>5</sup> For example, the fourth quarter of 2012 witnessed the highest amount of recall activity experienced in the past couple of years, averaging six recalls per day and a total 552 recalls of FDA regulated foods.<sup>6</sup> A recent Centers for Disease Control and Prevention (CDC) study of the causes of foodborne illness found plant foods responsible for the largest percent (46%) of foodborne illness with livestock and poultry responsible for the most deaths.<sup>7</sup> In 2009 the CDC admitted, “Despite numerous activities aimed at preventing foodborne human infections . . . progress toward the national health objectives has plateaued, suggesting that fundamental problems with bacterial and parasitic contamination are not being resolved.”<sup>8</sup> A recent report found that foodborne illness among the most common pathogens results in a \$77.7 million economic burden in the United States each year.<sup>9</sup>

Historically, improper handling of food was the main cause of foodborne illness and resulted in dozens, or fewer, of illnesses from any particular out-

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*nella* During Past 15 Years (June 7, 2011), available at [http://www.cdc.gov/media/releases/2011/p0607\\_vitalsigns.html](http://www.cdc.gov/media/releases/2011/p0607_vitalsigns.html) (announcing ten percent increase).

4. CAROLINE SMITH DEWAAL & DAVID W. PLUNKETT, CTR. FOR SCI. IN THE PUB. INTEREST, BUILDING A MODERN FOOD SAFETY SYSTEM FOR FDA REGULATED FOODS 5 (2009), available at <http://www.cspinet.org/new/pdf/fswhitepaper.pdf>; see also *Foodborne Outbreak Online Database (FOOD)*, U.S. FOOD & DRUG ADMIN., <http://wwwn.cdc.gov/foodborneoutbreaks/> (last visited Apr. 12, 2013) (logging illnesses by state, month, and etiology).

5. CAROLINE SMITH DEWAAL & MARCUS GLASSMAN, CTR. FOR SCI. IN THE PUB. INTEREST, OUTBREAK ALERT! 2001–2010, at 2 (2013), [http://cspinet.org/new/pdf/outbreak\\_alert\\_2013\\_final.pdf](http://cspinet.org/new/pdf/outbreak_alert_2013_final.pdf).

6. Press Release, Stericycle ExpertRECALL, An Average of Six Food Recalls Announced A Day During the Fourth Quarter of 2012, ExpertRECALL Index Shows (Feb. 14, 2013), available at <http://www.expertrecall.com/average-food-recalls-announced-day-fourth-quarter-2012-expertrecall-index-shows/>.

7. John A. Painter et al., *Attribution of Foodborne Illnesses, Hospitalizations, and Deaths to Food Commodities by Using Outbreak Data, United States, 1998–2008*, 19 EMERGING INFECTIOUS DISEASES 407, 410 (2013). Poultry was identified as the commodity with the most incidences of contamination. *Id.*

8. Ctrs. for Disease Control & Prevention, *Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly Through Food – 10 States, 2008*, 58 MORBIDITY & MORTALITY WEEKLY REP. 333, 336 (2009) [hereinafter *2008 Preliminary FoodNet Data*], available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5813a2.htm>.

9. Sandra Hoffmann et al., *Annual Cost of Illness and Quality-Adjusted Life Year Losses in the United States Due to 14 Foodborne Pathogens*, 75 J. OF FOOD PROTECTION 1292 (2012).

break.<sup>10</sup> Recent outbreaks have developed from contaminated equipment and unsafe food sources,<sup>11</sup> and have sickened thousands of people across large geographic areas.<sup>12</sup> “Meat and poultry carcasses can become contaminated during slaughter by contact with small amounts of intestinal contents,” while “fresh fruits and vegetables can be contaminated if they are washed or irrigated with water that is contaminated with animal manure or human sewage.”<sup>13</sup> Raw fruits and vegetables are of particular concern since high heat is not always used to kill harmful bacteria before consumption, and because the act of washing the produce may not destroy all harmful bacteria.<sup>14</sup>

The increased danger of contamination on fruits and vegetables is reflected in the news media, particularly in the past seven years. The first significant, nationwide produce outbreak resulted from contamination of California spinach with *Escherichia coli* O157:H7 in 2006, hospitalizing 205 people and killing three.<sup>15</sup> The spinach outbreak was followed by a nationwide recall of peanut butter due to *Salmonella* contamination in 2007,<sup>16</sup> another in 2008–2009 during an incident where contaminated products from King Nut Companies reached forty-six states and made 714 individuals ill,<sup>17</sup> and again in 2012 under the Sunland Peanut Butter Brand.<sup>18</sup> A *Salmonella* outbreak in 2008 affecting

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10. See BEN HEWITT, MAKING SUPPER SAFE: ONE MAN’S QUEST TO LEARN THE TRUTH ABOUT FOOD SAFETY 14–15 (2011).

11. See NICOLS FOX, SPOILED: WHY OUR FOOD IS MAKING US SICK AND WHAT WE CAN DO ABOUT IT 250 (Penguin Books 1998) (1997) (suggesting that “more careful skinning and slaughtering could help reduce the microbial load of beef”).

12. See HEWITT, MAKING SUPPER SAFE, *supra* note 10, at 15 (summarizing the scope and impact of major food illnesses from 2007–2010).

13. *Foodborne Illness: Frequently Asked Questions*, CTRS. FOR DISEASE CONTROL & PREVENTION, 8 (Jan 10, 2005), [http://www.cdc.gov/ncidod/dbmd/diseaseinfo/files/foodborne\\_illness\\_faq.pdf](http://www.cdc.gov/ncidod/dbmd/diseaseinfo/files/foodborne_illness_faq.pdf).

14. *Id.* at 9.

15. Press Release, U.S. Food & Drug Admin., FDA Finalizes Report on 2006 Spinach Outbreak (March 23, 2007), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2007/ucm108873.htm>.

16. Press Release, U.S. Food & Drug Admin., FDA Update on Peanut Butter Recall, (Mar. 9, 2007), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2007/ucm109585.htm>.

17. Press Release, U.S. Food & Drug Admin., King Nut Issues Peanut Butter Recall (Jan. 10, 2009), <http://www.fda.gov/Safety/Recalls/ArchiveRecalls/2009/ucm128692.htm>; see also SARAH A. LISTER & GEOFFREY S. BECKER, CONG. RESEARCH SERV., R40916, FOOD SAFETY: FOODBORNE ILLNESS AND SELECTED RECALLS OF FDA-REGULATED FOODS 11–12 (2010).

18. Press Release, U.S. Food & Drug Admin., Sunland, Inc. Announces Voluntary Limited Recall of Almond Butter and Peanut Butter Products Due to Possible Health Risk (Sept. 24, 2012), <http://www.fda.gov/safety/recalls/ucm320647.htm>; see also Helena Bottemiller, *Salmonella Peanut Butter Outbreak Expands; 35 Ill in 19 States*, FOOD SAFETY NEWS (Oct. 5, 2012),

peppers was traced back to a farm in Mexico,<sup>19</sup> while a 2010 *Salmonella* outbreak in Iowa eggs resulted in a 500 million egg recall.<sup>20</sup> Also in 2010, *Salmonella* was discovered in sprouts from an organic farm in Illinois causing illness in more than 100 people.<sup>21</sup> More recently, foodborne illness in the United States reached new proportions when a *Listeria monocytogenes* outbreak in cantaloupe claimed the lives of thirty-three people and one unborn child across twenty-eight states, becoming the most deadly foodborne illness outbreak in the United States since the 1920s.<sup>22</sup>

These and other national and regional outbreaks of smaller magnitude and lesser media coverage, but equal importance, have brought food safety to the attention of the general population and made food safety a top priority for Congress and President Obama.<sup>23</sup> Soon after entering office, Obama established the Food Safety Working Group “to provide advice on how to upgrade U.S. food safety laws, foster coordination throughout government, and ensure that food safety laws are effective and enforced.”<sup>24</sup> This simple measure was by no means the first attempt at addressing national food safety concerns.

#### A. *Food Safety History*

Food safety regulation began over one hundred years ago after publication of Upton Sinclair’s *The Jungle*, an exposé on careless practices of the meat

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[http://www.foodsafetynews.com/2012/10/salmonella-peanut-butter-outbreak-expands-35-ill-in-19-states/#.UUyc-r\\_3AwQ](http://www.foodsafetynews.com/2012/10/salmonella-peanut-butter-outbreak-expands-35-ill-in-19-states/#.UUyc-r_3AwQ).

19. Press Release, U.S. Food & Drug Admin., FDA Extends Consumer Warning on Serrano Peppers from Mexico, (July 30, 2008), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2008/ucm116929.htm>.

20. *Recall of Shell Eggs*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Safety/Recalls/MajorProductRecalls/ucm223522.htm> (last updated Oct. 18, 2010); see also Lyndsey Layton, *Iowa Egg Farmers Face Questions on Salmonella Outbreak*, WASH. POST, Sept. 22, 2010, <http://www.washingtonpost.com/wp-dyn/content/article/2010/09/22/AR2010092201331.html> [hereinafter Layton, *Egg Farmers Face Questions*].

21. Press Release, U.S. Food & Drug Admin., FDA: Don’t Eat Certain Lots of Tiny Greens Brand Alfalfa Sprouts or Spicy Sprouts (Feb. 16, 2011), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm238188.htm>; see also RENÉE JOHNSON, CONG. RESEARCH SERV., RL34612, FOOD SAFETY ON THE FARM 2 (2011) [hereinafter JOHNSON, FOOD SAFETY ON THE FARM].

22. *Multistate Outbreak of Listeriosis Linked to Whole Cantaloupes from Jensen Farms, Colorado*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/listeria/outbreaks/cantaloupes-jensen-farms/082712/index.html> (last updated Aug. 27, 2012).

23. See RENÉE JOHNSON, CONG. RESEARCH SERV., R41629, FOOD SAFETY ISSUES FOR THE 112TH CONGRESS 1 (2011) [hereinafter JOHNSON, ISSUES FOR CONGRESS].

24. *Id.*

processing industry.<sup>25</sup> The book, and the surrounding media attention, inspired President Roosevelt to take steps to protect consumers by supporting the passage of the Federal Meat Inspection Act<sup>26</sup> and the Pure Food and Drug Act.<sup>27</sup> The new legislation served to increase consumer confidence after intensified scrutiny caused a drastic drop in meat sales to ripple through the meat industry.<sup>28</sup> Current concerns about foodborne illness draw several parallels to the food safety movement a century ago. Many people, including producers and producer organizations, advocated for comprehensive regulatory reform to reestablish consumer confidence after the recent foodborne illness outbreaks.<sup>29</sup> Historically, the government relied on “education, cooperation, [] market-based incentives,” and voluntary implementation of good agricultural practice guidelines.<sup>30</sup> The occurrence of numerous and highly publicized foodborne illness outbreaks, however, provides reason to question whether relying on voluntary practices is sufficient to effectively protect consumers in a changed and vulnerable food system.

### B. Modern Response

The previously cited foodborne illness outbreaks and statistics set the stage for passage of the most significant food safety legislation since the Food, Drug, and Cosmetic Act of 1938 with the FDA Food Safety Modernization Act (FSMA).<sup>31</sup> President Obama signed FSMA into law on January 4, 2011, after overwhelmingly passing the Senate one month earlier with a recorded vote of seventy-three to twenty-five.<sup>32</sup> FSMA is most noteworthy for the increased regu-

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25. See generally UPTON SINCLAIR, *THE JUNGLE* (1906) (detailing the hazardous and unsanitary conditions in Chicago’s meat packing plants).

26. Federal Meat Inspection Act of 1906, ch. 3913, 34 Stat. 674 (1906) (codified as amended at 21 U.S.C. §§ 601–695 (2006 & Supp. V 2011)).

27. Pure Food and Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (1906) (codified as amended at 21 U.S.C. §§ 301–399 (2006)).

28. *Upton Sinclair’s The Jungle: Muckraking the Meat-Packing Industry*, 24 BILL OF RIGHTS IN ACTION (Const. Rights Found., L.A., Cal.), Spring 2008, <http://www.crf-usa.org/bill-of-rights-in-action/bria-24-1-b-upton-sinclairs-the-jungle-muckraking-the-meat-packing-industry.html>.

29. See Letter from Am. Feed Indus. Ass’n et al. to Sen. Harkin & Sen. Enzi (Nov. 15, 2010), available at <http://www.meatami.com/ht/a/GetDocumentAction/i/64238>.

30. RENÉE JOHNSON, CONG. RESEARCH SERV., R40443, FDA FOOD SAFETY MODERNIZATION ACT (P.L. 111-353) 13 (2011) [hereinafter JOHNSON, FSMA].

31. JOHNSON, FEDERAL FOOD SAFETY SYSTEM, *supra* note 1, at 2; see Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040 (codified as amended at 21 U.S.C. §§ 301–399); FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat 3885 (codified in scattered sections of 21 U.S.C. (Supp. V 2011)).

32. 156 CONG. REC. S8267 (daily ed. Nov. 30, 2010); JOHNSON, FEDERAL FOOD SAFETY SYSTEM, *supra* note 1, at 7.

latory authority it provides FDA in working to prevent foodborne illness through increased inspection frequencies, higher compliance standards, preventive controls, new tools to ensure imported food is safe, and enhanced response authority for foodborne illness outbreaks.<sup>33</sup> FSMA also demonstrates a paradigm shift in thinking about food safety, moving from a reactionary to a preventive approach.<sup>34</sup> FSMA is meant to modernize food safety regulations that some suggest have not kept pace with the changing nature of agriculture and food production in recent decades.<sup>35</sup> The original language of FSMA, however, did not satisfy all food safety supporters, particularly small farm and food facility advocates who feared the regulatory burden that could result from implementation of the new regulations required under FSMA.<sup>36</sup> The central issue was whether the costs associated with the increased regulatory burden were justified in light of the food safety benefits that resulted.<sup>37</sup> In response to those concerns, Senator Jon Tester of Montana, with Senator Kay Hagen as co-sponsor, introduced an amendment to FSMA to exempt small farmers and food facilities from the produce safety standards and the Hazard Analysis and Risk Prevention Controls requirement if the farm or food facility met qualifying criteria.<sup>38</sup> The addition of the Tester Amendment provisions satisfied many small farm advocates, but nevertheless drew criticism from industry groups upset that not everyone would be required to adhere to the new standards, and even a few small farm advocates who believed the addition of the Tester Amendment would still be insufficient to limit the potential regulatory burden that might result.<sup>39</sup> FSMA still gathered enough votes,

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33. See, e.g., 21 U.S.C. § 350j (Supp. V 2011) (inspection frequencies); *id.* § 350g (hazards analysis); *id.* § 350h (preventive controls); *id.* § 381 (imports); *id.* § 2202 (response authority).

34. Press Release, U.S. Food & Drug Admin., FDA Food Safety Modernization Act: Putting Ideas into Action (Jan. 27, 2011), <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/ucm241192.htm>.

35. JOHNSON, ISSUES FOR CONGRESS, *supra* note 23, at 1–2.

36. See, e.g., Letter from Acres USA et al. to U.S. Senators (June 10, 2010), *available at* [http://www.nffc.net/Pressroom/Letters/2010/S510\\_%20letter\\_June\\_10.pdf](http://www.nffc.net/Pressroom/Letters/2010/S510_%20letter_June_10.pdf) (letter signed by 157 consumer, farmer, and rancher organizations encouraging amendments for small-scale, local producers); *see also* Interview by Annie Corrigan with Joel Salatin, author, Folks, This Ain't Normal (Oct. 11, 2011), *available at* <http://indianapublicmedia.org/eartheats/joel-salatin-part-2-food-regulation-little-guy/> (describing fear among small farmers and producers and general hesitation with government regulations on food production).

37. JOHNSON, FOOD SAFETY ON THE FARM, *supra* note 21, at 15.

38. *Id.* at 22–23.

39. Compare Letter from United Fresh Produce Ass'n et al. to Sen. Reid et al. (Nov. 18, 2010), *available at* <http://www.unitedfresh.org/assets/files/Letter%20on%20Passage%20of%20S%20%20510%20and%20Tester%20Amendment.pdf> (industry opposition), with Judith McGeary, *Analysis of the Tester-Hagan Amendment*, FARM & RANCH FREEDOM ALLIANCE (Dec. 2, 2010), <http://farmandranchfreedom.org/analysis-of-the-tester-hagan-amendment/> (suggesting the Tester



even with inclusion of the Tester Amendment, to pass the Senate, but the legislation and added Tester Amendment provisions are not without critics.

This Note focuses on the potential effects FSMA may have on small farmers and food processors, and whether the provisions of FSMA and the Tester Amendment are sufficient to protect and grow the vitality of small farmers and food processors nationwide and the local markets they are more frequently beginning to serve. Part II provides background on FSMA and the Tester Amendment, highlighting the specific provisions of the Tester exemption. Part III discusses the weaknesses of the Tester Amendment, and FSMA as a whole, in protecting the vitality of small farmers and food processors. Part IV provides suggestions for alternative approaches in providing a safe food supply while at the same time promoting the vitality of small farms and food processors as they struggle to compete with large players in the industry in the face of un-scaled regulations. Finally, the conclusion in Part V calls for further examination of other un-scaled legislation that inhibits local food production, processing, and distribution, in an effort to strengthen local food systems and rural economies.

This Note does not advocate for the end of all government food safety regulations for farmers and food processors of any particular size. It recognizes, however, inherent weaknesses in the chosen approach to food safety under FSMA and the Tester Amendment and the need for greater efforts in finding a smart and economical balance between providing the necessary government oversight and promoting the success of small farms and food processors and the local markets they serve. Successful small farms and processors are a market essential if food choice, or “food democracy,”<sup>40</sup> is to be maintained. Though the Tester Amendment may save many small farmers and processors from regulation under some of FSMA’s most burdensome provisions, greater gains can and must be made to preserve, promote, and re-grow alternative food production models.

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Amendment is “damage control” at best) and Interview by Corrigan with Salatin, *supra* note 36 (calling food safety advocates “well-intentioned but naïve”).

40. Neil Hamilton, *Food Democracy and the Future of American Values*, 9 DRAKE J. AGRIC. L. 9, 16 (2004) (describing food democracy as “people wanting more: consumers wanting more information about their food . . . farmers wanting more for the futures of their children . . . chefs and eaters wanting better tasting, fresher, more wholesome and more nutritious food”).



## II. BACKGROUND ON THE FOOD SAFETY MODERNIZATION ACT AND THE TESTER AMENDMENT

### A. *FSMA Objectives and Provisions Potentially Affecting Small Farmers and Food Processors*

FSMA provides FDA with more regulatory power in the areas of preventive controls, inspection and compliance, imported food safety, response ability, and enhanced partnerships with other food safety regulators.<sup>41</sup> Of these provisions, preventive controls are most likely to affect farmers and food processors and will therefore remain the focus of this Note.<sup>42</sup> Preventive control measures can be subdivided into the primary categories of produce safety standards and the Hazards Analysis and Risk Prevention Controls (HARPC) program.<sup>43</sup>

### B. *Produce Safety Standards*

Produce safety standards are science-based standards covering the growing and handling of types of fruits and vegetables that either have a history of producing foodborne illness outbreaks or remain at risk to do so in the future.<sup>44</sup> Unlike HARPC, which primarily affects food facilities, this provision most directly effects on-the-farm activity.<sup>45</sup> The Secretary of Health and Human Services (HHS) working with the Secretary of Agriculture is “to establish science-based minimum standards for the safe production and harvesting of . . . fruits and vegetables . . . for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death.”<sup>46</sup> The standards the Secretary will propagate include standards pertaining to “growing, harvesting, sorting, packing, and storage operations” and “science-based minimum standards related to soil amendments, hygiene, packaging, temperature controls, animals in the growing area, and water.”<sup>47</sup> The Secretary is also to “consider hazards that occur naturally, may be unintentionally introduced, or may be intention-

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41. *Food Safety Modernization Act (FSMA): Frequently Asked Questions*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm> (last updated Mar. 26, 2013).

42. 21 U.S.C. §§ 350g, 350h (Supp. V 2011); *see also* JOHNSON, FSMA, *supra* note 30, at 15.

43. JOHNSON, FSMA, *supra* note 30, at 7, 12.

44. *See id.* at 7.

45. *Id.*

46. 21 U.S.C. § 350h(a)(1)(A) (Supp. V 2011).

47. *Id.* § 350h(a)(3)(B).

ally introduced, including by acts of terrorism.”<sup>48</sup> Overall, the standards are aimed at preventing the introduction of biological, chemical, and physical hazards whether introduced unintentionally or intentionally.<sup>49</sup> Once promulgated, farmers will have to adhere to the produce safety standards for each crop grown that falls under the standards unless it meets the necessary criteria to fit within the Tester Amendment exemption.<sup>50</sup> Alternatively, farms with an average annual monetary value of food sold during the previous three year period of less than \$25,000 are not “covered farms” under the proposed regulations and therefore would not be subject to the produce standards.<sup>51</sup> Farms that fall within the definition of a small business or very small business, to be defined by FDA, will have extra time to comply with the new standards.<sup>52</sup> FDA is charged with bearing in mind the variability in farm and business sizes and providing “sufficient flexibility to be practicable for all sizes and types of business” when establishing necessary rules.<sup>53</sup>

Despite the specific language dictating that FDA consider the size of farms when drafting the required rules, small farmers and small farm organizations raised concern over the potential produce safety standards and whether FDA would promulgate the rules in a helpful manner.<sup>54</sup> This collective concern aided in the successful inclusion of the Tester Amendment to *guarantee* certain protections to qualifying entities.<sup>55</sup> The Tester Amendment provides an exemption from the produce safety standards if a farm can demonstrate a previous three-year average gross income of less than \$500,000 and over 50% of sales were to qualified end users.<sup>56</sup> Qualified end users are defined as either the direct consumer of the food or a restaurant or retail food establishment in the same state or within 275 miles of the farm.<sup>57</sup> Additionally, farms must display the address of the farm either on the product or at the point of purchase.<sup>58</sup> Finally, FDA can

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48. *Id.* § 350h(a)(3)(C).

49. *Id.* § 350h(c)(1)(A).

50. *Id.* § 350h(a)(1)(B), (f); *see also* JOHNSON, FSMA, *supra* note 30, at 15.

51. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 78 Fed. Reg. 3504, 3632 (proposed Jan. 16, 2013) (to be codified at 21 C.F.R. § 112.4). Farms under this cutoff comprise an estimated 1.5% of covered produce acres. *Id.*

52. 21 U.S.C. § 350h(b)(3). Small businesses would be given three years and very small businesses four years to comply under the proposed rules. 78 Fed. Reg. at 3534. The proposed rules define “small business” as a farm earning less than \$500,000 (89% of produce farms) and “very small business” as farms earning less than \$250,000 (83% of produce farms). *Id.* at 3544.

53. 21 U.S.C. § 350h(c)(1)(B).

54. *See, e.g.*, Interview by Corrigan with Salatin, *supra* note 36.

55. JOHNSON, FOOD SAFETY ON THE FARM, *supra* note 21, at 22.

56. 21 U.S.C. § 350h(f)(1).

57. *Id.* § 350h(f)(4)(A).

58. *Id.* § 350h(f)(2)(A).

remove the exemption in the event of a foodborne illness outbreak investigation linked to a farm's produce.<sup>59</sup>

### C. Hazards Analysis and Risk Prevention Controls

Next, HARPC standards provide FDA with power to mandate food processing facilities undergo a hazards analysis by conducting an analysis of the most likely food safety hazards in the manufacturing, processing, and packaging steps of production, and then design and implement the hazard controls to prevent contamination of the food.<sup>60</sup> This regulation is similar to the Hazard Analysis and Critical Control Point (HACCP) scheme used in the meat and poultry industries.<sup>61</sup> Food facilities are the primary target under HARPC, but farms may be subject to HARPC requirements if they carry out certain processing activities on the farm and are not regulated under produce safety standards, making this provision of interest to many small farmers.<sup>62</sup> The law requires each facility undertake a hazards analysis, identify and implement preventive controls, develop a written analysis, monitor effectiveness of the controls, take corrective actions when controls fail, provide verification of the above processes, keep written records, and reanalyze the system upon any modifications.<sup>63</sup> Hazards can include "biological, chemical, physical, and radiological hazards, natural toxins, . . . parasites, allergens, and unapproved food and color additives."<sup>64</sup> Preventive controls are scientific- and risk-based practices that "facilities use to prevent foodborne hazards [listed above] that their products might contain."<sup>65</sup> Examples of necessary procedures and practices considered preventive controls may include "[s]anitation procedures for food contact surfaces and utensils," hygiene training, a food allergen control program, a recall plan, and supplier verification activities.<sup>66</sup>

FSMA gives FDA discretion to define a "very small business," which would be eligible for an exemption from the HARPC requirements.<sup>67</sup> The proposed HARPC rule currently presents three options for defining "very small

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59. *Id.* § 350h(f)(3)(A).

60. *Id.* § 350g(a).

61. See 21 C.F.R. §§ 120.1–.25 (2012); see also JOHNSON, FSMA, *supra* note 30, at 12.

62. See 21 U.S.C. § 350g(k); see also JOHNSON, FOOD SAFETY ON THE FARM, *supra* note 21, at 11.

63. 21 U.S.C. § 350g.

64. *Id.* § 350g(b)(1)(A).

65. *Food Safety Modernization Act (FSMA): Frequently Asked Questions*, *supra* note 41.

66. 21 U.S.C. § 350g(o)(3)(A)–(B), (D)–(E), (G).

67. *Id.* § 350g(n)(1)(B); (l)(1)(B).

business.”<sup>68</sup> FDA is considering cutoffs at \$250,000, \$500,000, or \$1 million in total annual sales of foods and is seeking comments on the appropriate amount.<sup>69</sup> In addition to the estimated 11,500 food processing facilities that would qualify for exempt status under the Tester Amendment provisions, the proposed cut-offs defining “very small business” will exempt 34,600, 45,900, or 63,500 additional food facilities respectively.<sup>70</sup> Because qualifications under the Tester Amendment require food facilities to have less than \$500,000 in sales with more than 50% of sales to qualified end users, the \$250,000 option would provide a similar cutoff.<sup>71</sup> Though these numbers may seem large, the food facilities that would qualify under each cut-off are less than half a percent, less than one percent, and less than two percent of all food facilities respectively.<sup>72</sup>

The HARPC provision also includes a similar exemption from the Tester Amendment.<sup>73</sup> In addition to meeting the same qualifying criteria (less than \$500,000 in sales with more than 50% of sales to qualified end users), to be eligible for the exemption a facility is required to show:

- (i)(I) documentation that demonstrates that the owner, operator, or agent in charge of the facility has identified potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the preventive controls to ensure that such controls are effective; or
- (II) documentation . . . that the facility is in compliance with State, local, county, or other applicable non-Federal food safety law; and
- (ii) documentation . . . that the facility is a qualified facility under paragraph (1)(B) or (1)(C).<sup>74</sup>

This exemption can also be withdrawn in the event of a foodborne illness outbreak resulting from food produced or handled at the facility.<sup>75</sup>

Following the amended guidelines of the Federal Food, Drug, and Cosmetic Act, a facility is defined as “any factory, warehouse, or establishment . . .

68. Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, 78 Fed. Reg. 3646, 3701 (proposed Jan. 16, 2013) (to be codified in scattered sections of 21 C.F.R.).

69. *Id.*

70. *Id.* at 3702.

71. *Id.* The difference in the estimated number of qualified users under the proposed “very small business” exemption in contrast to the Tester Amendment exemption is likely due to the fact that the Tester exemption is more limited due to the geography restrictions included in the provision.

72. *Id.*

73. 21 U.S.C. § 350g(l).

74. *Id.* § 350g(l)(2)(B)(i)–(ii).

75. *Id.* § 350g(l)(3)(A).

that manufactures, processes, packs, or holds food.”<sup>76</sup> Processing food includes peeling, cutting, bottling, freezing, and milling along with the more obvious baking and cooking.<sup>77</sup> Under that definition, any unregulated farm that undertakes any of these activities—often considered value-added activities—falls under the umbrella of an “establishment” and must adhere to the HARPC requirements unless they fit within the exemption.<sup>78</sup> For example, a non-exempt farmer growing potatoes who wanted to clean and cut the potatoes into hash browns before sale to a local grocery store chain would be required to follow HARPC guidelines.

#### D. *Support for the Tester Amendment*

The Tester Amendment exemptions outlined in Parts II.B and II.C grew from the concerns of Senator Tester and the vocal efforts of many small farmers and farmer organizations across the country, who recognized the likely or potential consequences to local food production if FSMA passed without special guaranteed protections for those operations.<sup>79</sup> Fears included the added regulatory burden that could result, the wide reach of the law, and the discretion given to FDA when implementing the law.<sup>80</sup> Tester argued, “Family farms and ranches have enough hurdles to jump over just trying to make a living. They don’t need expensive, redundant regulation that could put them out of business.”<sup>81</sup> Other reasons for including an exemption for small farmers included the greater accountability inherent in local food supply chains, the easier traceability, and the

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76. *Id.* § 350d(c)(1).

77. 21 C.F.R. § 1.227(b)(6) (2012); *see also* 78 Fed. Reg. 3646, 3679 (proposed Jan. 16, 2013) (to be codified in scattered sections of 21 C.F.R.); Organic Farming Research Found., *Food Safety Frequently Asked Questions*, NAT’L SUSTAINABLE AGRIC. COAL., 3 (June 13, 2011), <http://sustainableagriculture.net/wp-content/uploads/2011/06/NSAC-Food-Safety-FAQ-June-2011.pdf>. “Washing, trimming of outer leaves of, and cooling produce are considered part of harvesting,” rather than processing, and farms that undertake these very basic activities would not fall within the HARPC facility regulations. 21 C.F.R. § 1.227(b)(3) (2012).

78. Organic Farming Research Found., *supra* note 77, at 3–4.

79. *See, e.g.*, Letter from Acres USA et al. to U.S. Senators, *supra* note 36.

80. 156 CONG. REC. S8010 (daily ed. Nov. 18, 2010) (statement of Sen. Tester); *see also* Margie MacDonald & Judith McGeary, *S. 510 Food Safety Modernization Act, Healthy Local Foods Amendment—Senators Jon Tester and Kay Hagan*, W. ORG. OF RES. COUNCILS, 2, [http://www.worc.org/userfiles/file/Local%20Foods/QA\\_Testers\\_Amendment.pdf](http://www.worc.org/userfiles/file/Local%20Foods/QA_Testers_Amendment.pdf) (last visited Apr. 12, 2013).

81. Press Release, Sen. Jon Tester, Tester to Introduce “Common Sense” Amendments to Food Safety Bill (Apr. 14, 2010), *available at* [http://tester.senate.gov/?p=press\\_release&id=1106](http://tester.senate.gov/?p=press_release&id=1106).

lower risk of widespread foodborne illness outbreaks;<sup>82</sup> echoing similar ideas promoted by agrarian author Wendell Berry, who wrote,

[i]n a highly centralized and industrialized food-supply system there can be no small disaster . . . [T]he disaster is not foreseen until it exists; it is not recognized until it is widespread. By contrast, a highly diversified, small-farm agriculture combined with local marketing is literally crisscrossed with margins, and these margins work both to allow and encourage care and to contain damage.<sup>83</sup>

Amendment proponents were most frustrated by the original language of FSMA because it outlined a “one-size-fits-all approach, and when its [sic] one size fits all, it’s usually written by the big guy.”<sup>84</sup> Farmer, author, and local food advocate Joel Salatin, featured in the documentary *Food Inc.* and Michael Pollan’s book *Omnivore’s Dilemma*, explains,

Every time the culture decides through popular vote to ask for government penetration into the marketplace, it creates a climate that pushes the biggest players to curry concessionary privileges with the regulators. The little players don’t have the clout, manpower, or capital to arm-twist. The big players do. And that is why every time . . . the public asks for government oversight, it eventuates in the bigger players getting more power and the smaller players being kicked in the teeth.<sup>85</sup>

Small farmers feared the potential burden that could result from implementation of the produce safety standards if required to adhere to a strict regulatory scheme for each crop grown and argued the costly and burdensome proposals could not be justified considering the minimal public health protections that would result.<sup>86</sup> Small farmers compared the likely consequences of produce safety standards for different sized farms. They argued that smaller, diversified producers with dozens of different crops would require different practices, standards, and precautions for each regulated crop.<sup>87</sup> In contrast, larger producers frequently only grow one or two select crops and have the available resources to implement one set of targeted standards without significant consequence to their

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82. 156 CONG. REC. S8010 (statement of Sen. Tester).

83. WENDELL BERRY, *THE UNSETTLING OF AMERICA: CULTURE & AGRICULTURE* 223 (1977) [hereinafter BERRY, *THE UNSETTLING OF AMERICA*].

84. Taryn Luntz, *Small Farms Fear Bearing Brunt of New Food Safety Regulations*, N.Y. TIMES, Apr. 3, 2009, <http://www.nytimes.com/gwire/2009/04/03/03greenwire-small-farms-fear-bearing-brunt-of-new-regulati-10431.html> [hereinafter Luntz, *Small Farms Fear*].

85. JOEL SALATIN, *FOLKS, THIS AIN’T NORMAL* 338 (2011) [hereinafter SALATIN, *THIS AIN’T NORMAL*]. See generally MICHAEL POLLAN, *THE OMNIVORE’S DILEMMA: A NATURAL HISTORY OF FOUR MEALS* (2006) [hereinafter POLLAN, *OMNIVORE’S DILEMMA*]; *FOOD, INC.* (Magnolia Pictures 2008).

86. JOHNSON, *FOOD SAFETY ON THE FARM*, *supra* note 21, at 15.

87. Luntz, *Small Farms Fear*, *supra* note 84.

bottom line.<sup>88</sup> Additionally, amendment supporters emphasized that farmers, who already spend most of their days during the growing season working would rather be in the fields than doing paperwork, more of which would be required under FSMA.<sup>89</sup>

Amendment supporters cited broad FDA discretion in rule and definition making as another potential threat to small farmers.<sup>90</sup> While FSMA cautions FDA to take scale of production into consideration, any rule or definition promulgated by FDA and later challenged if small farmers disagree is likely to be upheld under the broad deference given to administrative agency decisions under the arbitrary and capricious standard.<sup>91</sup> The original language of the bill provided no definite or specific protections to small farmers and food processors.<sup>92</sup>

The most common refrain sung by amendment supporters emphasized the greater accountability inherent in localized food systems.<sup>93</sup> Small farm advocates argued the close relationship consumers have with small farms increases the level of accountability.<sup>94</sup> Implied in this claim is that greater accountability leads to a safer food source and can be just as effective, if not more effective, in assuring food safety than regulations aimed toward the same end under the guise of FSMA. This was the core argument supporting the exemption, but amendment supporters went even further, emphasizing more efficient traceability and the limited effects a foodborne illness outbreak would have in a regional distribution system, compared to the nationwide system bigger producers rely on.<sup>95</sup> Senator Tester argued to Congress,

If a mistake is made . . . it doesn't impact hundreds of thousands of people. We know exactly where the problem was and we know exactly how to fix it. So the traceability of the outbreaks is immediate and is taken care of without impacting 20 or 30 States and hundreds of thousands of people.<sup>96</sup>

Nationally renowned foodborne illness attorney William Marler jokingly admitted that “just because you can shake the hand of the guy who sold you

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88. *Id.*

89. 156 CONG. REC. S8010 (daily ed. Nov. 18, 2010) (statement of Sen. Tester).

90. *See, e.g., Will the Food Safety Modernization Act Harm Small Farms or Producers?*, GRIST (Nov. 16, 2010), <http://www.grist.org/article/food-2010-11-15-food-fight-safety-modernization-act-harm-small-farms/PALL> (discussing broad discretion given by courts to agencies in decision-making).

91. *See Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843–45 (1984).

92. *See* 21 U.S.C. §§ 350g(n)(3)(A), 350h(a)(3)(A) (Supp. V 2011).

93. 156 CONG. REC. S8010 (statement of Sen. Tester).

94. Letter from Acres USA et al. to U.S. Senators, *supra* note 36.

95. *Id.*

96. 156 CONG. REC. S8010 (statement of Sen. Tester).



your dinner doesn't mean he's not going to poison you. But it does mean you'll know where to find him if he does."<sup>97</sup> In summary, amendment supporters questioned whether the added costs to small farmers and processors under the original language of FSMA were justified by the purported health benefits.<sup>98</sup>

#### E. *Opposition to the Tester Amendment*

Industry groups that initially supported FSMA spoke out against the proposed inclusion of the Tester Amendment.<sup>99</sup> In a letter to Senators Harkin and Enzi, signed by thirty producer organizations, they stated, "We believe an operation's size, the growing practices used, or its proximity to customers does not determine whether the food offered is safe."<sup>100</sup> They make clear the desire to restore confidence in the nation's food supply and argue all segments of the food system should be held to strict standards of food safety or public confidence will remain weak and hamper sales for everyone.<sup>101</sup> Senator Chambliss called the Tester Amendment "arbitrary" and a "loophole" that risked injecting contaminated products from exempt farms into an otherwise highly regulated and safe supply system, adversely affecting all producers.<sup>102</sup>

Further, opponents believed FSMA as originally drafted contained sufficient provisions to protect the interest of small farmers and food processors.<sup>103</sup> For example, the bill exempted very small businesses from new record keeping requirements and gave them extra time to come into compliance.<sup>104</sup> It also left previous protections in place, like the narrow definition of "facility" that does not include certain farms and restaurants.<sup>105</sup>

Despite industry opposition, FSMA passed by a vote of seventy-three to twenty-five in the Senate and included the Tester Amendment and its protections

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97. HEWITT, MAKING SUPPER SAFE, *supra* note 10, at 67.

98. JOHNSON, FOOD SAFETY ON THE FARM, *supra* note 21, at 15.

99. 156 CONG. REC. S8225 (daily ed. Nov. 29, 2010) (statement of Sen. Chambliss) (citing industry support for original Act and subsequent opposition to proposed Tester Amendment); see Letter from Am. Feed Indus. Ass'n et al. to Sen. Harkin & Sen. Enzi, *supra* note 29.

100. Letter from Am. Feed Indus. Ass'n et al. to Sen. Harkin & Sen. Enzi, *supra* note 29.

101. *Id.*

102. 156 CONG. REC. S8225 (statement of Sen. Chambliss); see also Robert Guenther, *Why Wasn't Tester Tested?*, PRODUCE BUS., Feb. 2011, at 6 (quoting California U.S. Rep. Sam Farr as saying, "[i]f we allow small producers to avoid oversight, the outbreaks that are likely to occur will result in the harm of all growers, handlers, processors, and shippers").

103. 156 CONG. REC. S8225 (statement of Sen. Chambliss) ("[S]mall businesses are given regulatory flexibility throughout the original version of S. 510.").

104. 21 U.S.C. §§ 350g(l)(1)(B)(i), (l)(2), 350h(b)(3) (Supp. V 2011).

105. 156 CONG. REC. S8225 (statement of Sen. Chambliss).

for small entities.<sup>106</sup> Senator Whitehouse described the final product, saying, “This is not a perfect bill, but it is a necessary one.”<sup>107</sup> Most small farm supporters saw the inclusion of the Tester Amendment as a victory for local and independent food,<sup>108</sup> but most importantly, the inclusion of small entity protections marked a formal recognition by Congress that one size does not fit all when dealing with farm and food regulations. Nevertheless, the exact effects FSMA and the Tester Amendment will have on small farms are still speculative due to unknown variables, including the final results of FDA rulemaking,<sup>109</sup> further research outlining the extent of qualifying farms, and FDA enforcement capabilities. Though the exemption may have saved some small entities from regulations, critics argue the Tester Amendment was “damage control” at best.<sup>110</sup> Even with inclusion of the Tester Amendment, the end-result for many small entities includes new restrictions on their market freedom, a few new hurdles to jump, or, if they fail to qualify for the Tester Amendment entirely, significant new regulations.

### III. WEAKNESSES OF THE TESTER AMENDMENT AND FSMA

Despite broad consensus that passage of FSMA served as a long overdue update to century old food safety regulations, weaknesses in the approach taken by FSMA in general, and Tester Amendment more specifically, are evident. These weaknesses range from technical aspects of the amendment itself to the much broader methodology and principles underlying the newly adopted approach to produce food safely. In trying to craft a new food safety system, it is logically imperative that consumer health and safety is the ultimate goal. The challenges lie in developing an effective way to meet that goal while allowing for a variety of production methods to suit the growing diversity of needs and desires of both consumers and producers. While the Tester Amendment was successfully inserted into FSMA to protect small entities from damaging regulatory burdens, it is far from perfect. Further consideration of this issue is important. Many industry and consumer groups opposed the exemptions carved out by the

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106. 156 CONG. REC. S8267 (daily ed. Nov. 30, 2010).

107. *Id.* at S8265 (statement of Sen. Whitehouse).

108. See *Tester Amendment Now a Part of the Food Safety Bill*, BEGINNING FARMERS (Nov. 21, 2011), <http://www.beginningfarmers.org/tester-amendment-now-a-part-of-the-food-safety-bill>.

109. 78 Fed. Reg. 3504 (proposed Jan. 16, 2013) (to be codified in scattered sections of 21 C.F.R.); 78 Fed. Reg. 3646 (proposed Jan. 16, 2013) (to be codified in scattered sections of 21 C.F.R.).

110. McGeary, *supra* note 39.

Tester Amendment.<sup>111</sup> It is likely food safety issues will be resurrected and small entities threatened again by further regulation, *especially* if FSMA yields insufficient results. Furthermore, helpful lessons can be learned from FSMA and applied to improve other regulations affecting small farms and food processors. The following sections of this Note perform a critical analysis of these weaknesses and provide alternative ideas for creating a safe food system that encourage broad and diverse participation among farmers and food processors.

### A. Regulatory Burden

#### 1. *History as a Guide: The Cost of Compliance*

Small farmers and food processors who have spoken in opposition of FSMA have legitimate reason to fear the effects of increased regulations if history is any guide. New regulations were placed on the meat processing industry in 1998, which required processors develop and implement a Hazard Analysis Critical Control Point (HACCP) program for each of their products.<sup>112</sup> Time required to implement a HACCP or similar plan can cost a business a significant amount of money.<sup>113</sup> Additionally, smaller, diversified facilities earning less profit are less able to absorb the expensive requirements and periodic testing for their diverse variety of products offered while larger, more specialized facilities require fewer and more targeted HACCP regulations.<sup>114</sup> One small abattoir cited a conservative estimate of \$100,000 in compliance costs incurred as a result of the requirements.<sup>115</sup> Even before implementation of the HACCP program, analysts predicted the rules and associated expenses would drive many small meat and poultry processors out of business, and the FSIS recognized small plants would be disproportionately affected by HACCP program costs.<sup>116</sup> Author Michael Pollan skeptically explains the government's willingness to allow for the

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111. See Letter from Am. Feed Indus. Ass'n et al. to Sen. Harkin & Sen. Enzi, *supra* note 29.

112. 21 C.F.R. §§ 120.1–.25 (2012); FOOD & WATER WATCH, WHERE'S THE LOCAL BEEF? REBUILDING SMALL-SCALE MEAT PROCESSING INFRASTRUCTURE 6 (2009), available at <http://documents.foodandwaterwatch.org/doc/WheresTheLocalBeef.pdf>.

113. FOOD & WATER WATCH, LOCAL BEEF, *supra* note 112, at 37–38.

114. *Id.*

115. *Id.* at 40.

116. U.S. GEN. ACCOUNTING OFFICE, GAO/RCED-95-228, MEAT AND POULTRY INSPECTION: IMPACT OF USDA'S FOOD SAFETY PROPOSAL ON STATE AGENCIES AND SMALL PLANTS 8 (1995), available at <http://gao.justia.com/departement-of-agriculture/1995/6/meat-and-poultry-inspection-rced-95-228/RCED-95-228-full-report.pdf> (citing INST. FOR FOOD SCI. AND ENG'G CTR., TEX. A&M UNIV., REFORMING MEAT AND POULTRY INSPECTIONS: IMPACTS OF POLICY OPTIONS (Apr. 1995)).

loss of smaller abattoirs as a matter of efficiency.<sup>117</sup> He argues it is easier for USDA to inspect and support large abattoirs than it is to shuffle inspectors between multiple regional facilities, a tactic that has special appeal in an era of shrinking resources.<sup>118</sup> Whether an intentional bias or not, the added compliance expenses make the survival of small processors even more challenging.<sup>119</sup>

Abattoirs are not the only businesses affected by un-scaled regulations. Participating vegetable growers in California must meet the requirements of the state's leafy greens marketing agreement, an industry and state government joint attempt at regulation in response to the widely publicized spinach outbreak in 2006.<sup>120</sup> Growers in California indicated compliance costs averaged \$18,000 per year.<sup>121</sup> In both instances the added costs of doing business provide an advantage to larger producers who are able to spread their compliance costs out over a larger quantity of product.

Economic impact analyses of the proposed rules already provide estimates of the pending expenses. FDA estimates the produce safety standards will cost domestic farms \$460 million annually, or \$5000 to \$30,000 per farm, depending on a farm's size.<sup>122</sup> Fruit growers argue the proposed rules will be "onerous and expensive," that FDA's approach in regulating produce "defies common sense," and that growers "'are being priced out of the business.'"<sup>123</sup> Some

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117. See Michael Pollan, *Farmer in Chief*, N.Y. TIMES, Oct. 9, 2008, <http://www.nytimes.com/2008/10/12/magazine/12policy-t.html?pagewanted=all>.

118. *Id.*

119. See *id.* (arguing the demise of local meat producers due to un-scaled regulations inhibits the success of local foods).

120. Cal. Leafy Green Handler Mktg. Bd., *Mission*, CALEAFYGREENS.GOV <http://www.caleafygreens.ca.gov/mission> (last visited Apr. 12, 2013). Farmers are not required to participate, but 99% of all leafy greens are grown under certification. Cal. Leafy Green Handler Mktg. Bd., *Certification*, CALEAFYGREENS.GOV <http://www.caleafygreens.ca.gov/certification> (last visited Apr. 12, 2013); see also CAL. LEAFY GREEN HANDLER MKTG. BD., COMMODITY SPECIFIC FOOD SAFETY GUIDELINES FOR THE PRODUCTION AND HARVEST OF LETTUCE AND LEAFY GREENS (2012) [hereinafter CAL. LEAFY GREEN], available at <http://www.caleafygreens.ca.gov/food-safety-practices#downloads>.

121. Lynn Byczynski, *Protecting Local Farms*, YES! MAG., Sept. 17, 2009, <http://www.yesmagazine.org/happiness/protecting-local-farms>.

122. U.S. FOOD & DRUG ADMIN., ANALYSIS OF ECONOMIC IMPACTS: STANDARDS FOR THE GROWING, HARVESTING, PACKING AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION 317–18 tbl.133 (2013), available at <http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM334116.pdf>.

123. Dennis Brady, *Proposed FDA Safety Rules Frustrate Tree Fruit Farmers*, WASH. POST, Apr. 9, 2013, <http://www.washingtonpost.com/> (search "frustrate tree fruit farmers"; then select "Proposed FDA Safety Rules Frustrate Tree Fruit Farmers" hyperlink).

even contend that if the proposed regulations take effect, they will leave the business.<sup>124</sup>

HARPC requirements are estimated to cost non-qualified food facilities \$13,000 to \$16,000 depending on the level of regulations included in the final rule.<sup>125</sup> Even qualified food facilities exempted from many of the new regulations are still expected to incur costs ranging from \$1000 to \$2000.<sup>126</sup> These added expenses are anything but trivial for small and mid-sized farmers and food processors unable to easily subtract the additional overhead from their profit margin.

## 2. *Confusing Language*

The problems with the burdensome costs cited above are partially irrelevant for farms and food processors successfully exempted under the Tester Amendment. A careful look at the language of FSMA and the Tester Amendment, however, suggests that small entities falling within the Tester exemption *may still* effectively be subject to some of the HARPC requirements, the same requirements these entities are supposed to be exempted from by the Amendment. FSMA requires the “owner, operator, or agent in charge of a facility” to “*identify and evaluate* known or reasonably foreseeable hazards.”<sup>127</sup> The owner shall also “*identify and implement* preventive controls”<sup>128</sup> and “*monitor* the effectiveness of the preventive controls.”<sup>129</sup> The exemption from the above responsibilities under FSMA requires food facilities to identify, evaluate, implement, and monitor and submit “documentation that demonstrates that the owner . . . has *identified potential hazards* associated with the food being produced, is *implementing preventive controls to address the hazards*, and is *monitoring* the preventive controls to ensure that such controls are effective.”<sup>130</sup> Alternatively, a facility can demonstrate they are in compliance with local and state laws if the state has implemented food safety laws.<sup>131</sup> Aside from substituting “identify and evaluate” for “identify,” a trivial substitution at best, the language is nearly identical. The desired effect of these provisions is unclear. Though the Tester Amendment was intended to limit restrictions placed on qualified entities under

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124. *Id.*

125. U.S. FOOD & DRUG ADMIN., ANALYSIS OF ECONOMIC IMPACTS 7–12, 172–73 tbl.60 (2013), available at <http://www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM334117.pdf>.

126. *Id.*

127. 21 U.S.C. § 350g(b) (Supp. V 2011) (emphasis added).

128. *Id.* § 350g(c) (emphasis added).

129. *Id.* § 350g(d) (emphasis added).

130. *Id.* § 350g(l)(2)(i)(I) (emphasis added).

131. *Id.* § 350g(l)(2)(B)(i)(II).

FSMA, the language of the Amendment provisions suggests there may still be similar requirements imposed on exempt entities.<sup>132</sup> FDA could reasonably interpret the nearly identical language to require these exempted small facilities to also identify potential hazards and employ HARPC-like measures against biological, chemical, physical, and other hazards FSMA was designed to address but the Tester Amendment was purported to exempt them from.<sup>133</sup> The exemption language does not require corrective action like FSMA does,<sup>134</sup> but the burden to small processors is not in correcting problems—as most processors would willingly address problems whether or not required by law. Instead, the hurdles erected through the identification, implementation, and monitoring stages pose the biggest regulatory challenge and qualifying facilities may not truly be exempted from these requirements.

Under the right conditions, small farms or processing facilities could receive little, if any, benefit from inclusion of the Tester Amendment and may instead face some of the challenges inherent in un-scaled regulations and experienced by abattoirs and California vegetable growers. For some this is hardly an exemption, and instead constitutes an additional obstacle. Independent of this, entities in states that do have their own food production regulations will continue to run into the regulation challenges presented by their local rules and the Tester Amendment exemption will provide little added benefit. Furthermore, qualified small entities are still not exempt from regulations for certain categories of high-risk foods.<sup>135</sup> While the current list is short,<sup>136</sup> the existence of such exclusions could set precedent for more, and subsequent amendments to FSMA adding more non-exempt items could threaten certain farmers and processors with added regulations no matter their size.

### 3. *Proving the Exemption*

If a farm or food facility successfully meets the requirements to be exempt under the Tester Amendment, reaping the rewards of exemption will necessarily require proving their exempt status, which may pose a significant burden on small entities where none existed before. The law itself does not specify how farms and processing facilities must claim an exemption or what documentation is necessary to verify an entity's qualifications, though implied is the presentation

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132. *See id.* § 350g(l)(2)(B).

133. *See id.* § 350g(b)(1)(A), (l)(2)(B).

134. *Compare id.* § 350g(e), with *id.* (l)(2)(B).

135. 21 U.S.C. § 350g(j), (l)(2)(A).

136. At present, the Tester exemption does not apply to seafood, juice, and low-acid canned facilities—facilities that are already subject to specific control programs and exempted from FSMA entirely. *Id.*

of tax records.<sup>137</sup> Providing proof of qualification will require more than submission of tax statements for the past three years, including details surrounding the volume of sales, the identity of purchasers, and the geographic distribution of their products in order to determine if they meet the 51% quota of products to qualified end users within the 275 mile limit, as outlined by the statute.<sup>138</sup> All of this implies the necessity to keep comprehensive records.<sup>139</sup> Even then, there might be questions as to whether a buyer is in fact a qualified end user depending upon how the Secretary chooses to define restaurant and retail food establishment. To the casual observer this simple requirement may seem inconsequential. For the busy small farmer or food processor, however, the added workload collecting, organizing, and analyzing the various criteria will have a direct impact on their ability to perform revenue generating activity.

#### 4. *Conflicting Values*

California's leafy greens regulations demonstrate the conflicts that can arise between different methods of agriculture and new food safety standards.<sup>140</sup> The California standards advocate practices that could include destruction of wild areas near agricultural crops to discourage wild animals from contaminating growing food.<sup>141</sup> Organic standards and other alternative agriculture principles require or encourage the growth of wild lands to promote a more natural ecosystem.<sup>142</sup> FSMA addresses this potential conflict and directs FDA to "not include any requirements that conflict with or duplicate the requirements of the national organic program" when drafting the rules and enforcing FSMA.<sup>143</sup> One can ques-

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137. See *FDA Food Safety Modernization Act: What Do the New Laws Mean for Small Farms and Producers?*, NEW ENG. FARMER'S UNION, 2, [http://newenglandfarmersunion.org/pdfs\\_docs/FoodSafety.pdf](http://newenglandfarmersunion.org/pdfs_docs/FoodSafety.pdf) (last visited Apr. 12, 2013) [hereinafter *What Do the New Laws Mean*].

138. 21 U.S.C. §§ 350g(l)(4)(B)(ii)(I), 350h(f)(1)(A).

139. *What Do the New Laws Mean*, *supra* note 137, at 2.

140. Craig Idlebrook, *Will Leafy Greens Safety Regulations Hurt Small Farmers?*, VTDIGGER.ORG (Sept. 15, 2011), <http://vtdigger.org/2011/09/15/will-leafy-greens-safety-regulations-hurt-small-farmers/>.

141. Luntz, *Small Farms Fear*, *supra* note 84; *National Leafy Greens Marketing Agreement*, OR. TILTH, <http://tilth.org/news/national-leafy-greens-marketing-agreement> (last visited Apr. 12, 2013). Subsequent revisions to the original leafy greens marketing agreement have recognized this conflict and adjusted the relevant language to avoid explicitly promoting environmental buffers. See CAL. LEAFY GREEN, *supra* note 120, at 45–46, 49–51 tbl.6. Studies have shown, however, that many producers employ food safety promotion tactics that harm environmental quality. Melanie Beretti & Diana Stuart, *Food Safety and Environmental Quality Impose Conflicting Demands on Central Coast Growers*, 62 CAL. AGRIC., 68–73 (2008) ("Growers of leafy greens were significantly more likely to be using bare-ground buffers . . .").

142. Luntz, *Small Farms Fear*, *supra* note 84.

143. 21 U.S.C. §350h(a)(3)(E).



tion how FDA can effectively regulate two inherently different methods of production under a common scheme when the requirements of one system are starkly at odds with those of the other. If the organic standards are followed, some of the expected, though not proven,<sup>144</sup> threats to contamination of the industrial food supply may go unchecked and food safety goals un-obtained. Meanwhile, certain regulations promoting industrial agriculture food safety are certain to undermine critical organic agriculture values.<sup>145</sup> Adding to the challenge is the fact that a large number of small farmers adhere to sustainable agriculture standards that are different, and oftentimes even more stringent, than organic standards. How will FDA consider these values and practices when drafting new rules? Drafting rules that take seriously the perceived food safety threat to crops but still respect the alternative methods of production being used under different farming structures and scales will be difficult, to say the least.

### B. *Line Drawing Challenges*

#### 1. *Under-Inclusive and Over-Inclusive*

Creating a distinction between small and large farms and facilities is inevitably both under-inclusive and over-inclusive at the same time. Farms and food processors small enough for the exemption but sloppy in their practices will be exempted, yet larger and more successful farmers and processors that produce safe food of high quality for local outlets will be required to follow the regulations. USDA's 2010 report on the structure and finances of U.S. farms shows that in 2007 slightly more than eighty percent of vegetables, fruits, and tree nuts were grown by farms grossing more than \$500,000<sup>146</sup> and therefore are ineligible for protection by the Tester Amendment. This figure rebuts common arguments opposing the amendment that suggest it exempts too much produce for FSMA to effectively restore confidence to the U.S. food supply. To put the cut-off into perspective and defray fears the exemption was too large, Senator Harkin noted,

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144. Many contest the theory that wildlife pose a significant threat to growing agricultural crops in the first place. See Bettina Boxall, *Wildlife Found to be Unlikely E. coli Culprit*, L.A. TIMES, Apr. 11, 2009, <http://articles.latimes.com/2009/apr/11/local/me-ecoli11> (quoting a biologist stating that “wildlife are not the Typhoid Marys some people think they are and some of the extreme measures are not necessary” after conducting a study on wild animals in California that found less than one percent of animals tested harbored *E. coli*); see also Beretti & Stuart, *supra* note 144, at 72 (“[M]ost studies on pastoral wildlife (associated with natural environments) do not illustrate a substantial threat to food safety.”).

145. See Luntz, *Small Farms Fear*, *supra* note 84.

146. See ROBERT A. HOPPE & DAVID E. BANKER, ECON. RESEARCH SERV., USDA, EIB-66, STRUCTURE AND FINANCES OF U.S. FARMS: FAMILY FARM REPORT, 2010 EDITION, at 10 fig. (2010), available at <http://www.ers.usda.gov/publications/eib66/eib66.pdf>.

“The smallest member of the California League of Food Processors reports between \$2.5 and \$3 million a year in sales or five times as much as any company eligible under the Tester provisions.”<sup>147</sup> Though the \$500,000 cut-off in the Tester exemption is large enough to capture almost twenty percent of fruit, vegetables, and tree nuts, it still leaves some small, local producers outside the exemption. For example, a 2011 study of Community Supported Agriculture (CSA) farms in California’s Central Valley found seven operations, or thirteen percent, grossing more than \$1,000,000 in sales out of the fifty-four farms studied.<sup>148</sup> CSA farms fit the purpose of the Tester Amendment because their business model uses hands-on methods to sell their food directly to local consumers. Joel Salatin has turned his farming enterprise into a “two-million-dollar-a-year food business,” well over the \$500,000 cut-off.<sup>149</sup> Many local food supporters would cite Salatin’s Polyface farm as the poster-child for safe and accountable local food, as Salatin sells the goods his farm produces either directly to local consumers or to local restaurants and allows anyone access to his farm at any time.<sup>150</sup>

Though the above citations give two examples of the under-inclusivity of the Tester Amendment, much remains unknown about the specific reach of the exemption.<sup>151</sup> FSMA included a provision requiring FDA to undertake a study to better understand the type and size of farm operations and the monetary value of food sold by each, the proportion of food sold by various sizes of farms, the number of farms that included food facilities, the incidences of foodborne illness from various economic classifications of U.S. farms, and risk factors associated with certain food handling practices.<sup>152</sup> The study was based on data from a private database and surveys administered to experts on the relevant topics.<sup>153</sup> The most relevant findings include the estimate that 1.9% of all food establishments considered in the study are co-located on farms and account for 1.71% of food sales.<sup>154</sup> The experts surveyed believed that all food categories have reported or

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147. 156 CONG. REC. S8266 (daily ed. Nov. 30, 2010) (statement of Sen. Harkin).

148. RYAN E. GALT ET AL., UNIV. OF CAL., DAVIS, COMMUNITY SUPPORTED AGRICULTURE (CSA) IN AND AROUND CALIFORNIA’S CENTRAL VALLEY: FARM AND FARMER CHARACTERISTICS, FARM-MEMBER RELATIONSHIPS, ECONOMIC VIABILITY, INFORMATION SOURCES, AND EMERGING ISSUES 4, 24 (2011), available at <http://asi.ucdavis.edu/resources/publications/Galt%20et%20al%20%202011-CSA%20Report.pdf>.

149. Allan Nation, *Foreword to SALATIN, THIS AIN’T NORMAL*, *supra* note 85, at ix.

150. SALATIN, *THIS AIN’T NORMAL*, *supra* note 85, at xi.

151. See JOHNSON, *FSMA*, *supra* note 30, at 16.

152. 21 U.S.C. § 350g(l)(5) (Supp. V 2011).

153. MARY K. MUTH ET AL., *FOOD PROCESSING SECTOR STUDY: FINAL REPORT*, at 2-1, 2-12, 3-1, 3-32–3-33 (2011).

154. *Id.* at 2-12, 2-16, 2-20.

known hazards,<sup>155</sup> and larger scale processing activities is “very or extremely important in contributing to foodborne illness risk.”<sup>156</sup> Researchers found no consistent pattern of which sizes of establishments (based on number of employees) contributed the most to foodborne illness.<sup>157</sup> By analyzing data according to the number of employees establishments have instead of an economic classification *based on income*, the study does not answer the most important question posed by FSMA: Do food processors with *lower income* have a better food safety record, making them worthy of the income-based exemptions provided in the Tester Amendment provisions?<sup>158</sup>

Leaving the study aside, before building a regulatory structure centered on income, we must ask the question: Are monetary sales, though convenient, the best measure of the risk of food safety? If the answer is no, and I believe it is, alternative methods are worth exploring. A mistake in this line drawing exercise could doom the fledgling local foods movement if a small farm, exempted under the Tester Amendment, were to cause a severe outbreak and suffer the likely assault from industry competitors and critical loss of consumer support. On the other hand, casting the exemption too narrow could create further disincentive for a small farmer or processors struggling to survive.

Amendment critics argue that “[s]mall farms are not inherently safe simply by virtue of their diminutive size,”<sup>159</sup> and “[t]he concept that small, local, organic equals safe and that large, global, multinational is unsafe is wrong.”<sup>160</sup> Supporters contend, however, that “[a]ll of the well-publicized incidents of contamination in recent years—whether in spinach, peppers, or peanuts—occurred in industrialized food supply chains . . . .”<sup>161</sup> Nationally-renowned food illness liti-

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155. *Id.* at 3-24. This finding may make it more difficult for FDA to exempt certain categories of “low risk” foods if no categories can truly be considered “low risk.” *See id.* at 3-23. *But see* 78 Fed. Reg. 3504, 3630 (proposed Jan. 16, 2013) (to be codified at 21 C.F.R. § 112.2) (proposing exemption of certain produce).

156. MUTH ET AL., *supra* note 153, at 3-29.

157. *Id.* at 3-22. The study’s authors urge caution in interpreting the foodborne illness data based on the wide range of responses. *Id.*

158. *See id.* FDA contends income is not a relevant measure “since facility income may be derived from multiple sources, many of which are not food-related.” 78 Fed. Reg. 3646, 7001 (proposed Jan. 16, 2013) (to be codified in scattered sections of 21 C.F.R.). Overall this study is underwhelming and provides weak insight into the questions posed in FSMA. *See* 21 U.S.C. § 350g(l)(5) (Supp. V 2011) (outlining objectives of study).

159. Alex Ferguson, Op-Ed., *What’s Wrong with the Tester Amendments*, FOOD SAFETY NEWS (May 4, 2010), <http://www.foodsafetynews.com/2010/05/whats-wrong-with-the-tester-amendments/>.

160. Helena Bottemiller, *Farmers Gain in Senate Food Safety Battle*, FOOD SAFETY NEWS (Apr. 15, 2010), <http://www.foodsafetynews.com/2010/04/farmers-make-gains-in-senate-battle/> (quoting David Acheson, former FDA Associate Commissioner of Foods).

161. MacDonald & McGeary, *supra* note 80, at 1.

gator Bill Marler stated, “In 16 years of doing this work, I’ve never sued a local farmer.”<sup>162</sup> A Government Accounting Office report cited modern animal husbandry methods, “such as crowding a large number of animals together,” as one of the primary factors contributing to increased foodborne illness rates, as studies examining the offending bacteria more and more often suggest.<sup>163</sup>

Though unlikely to solve this disagreement over sources of illness between the two methods of production anytime soon, further study and understanding of the food production and processing systems will likely yield greater insights over time.<sup>164</sup> In the meantime, however, it is already clear that successful farms fitting the purpose of the Tester Amendment may still fall outside the exemption it provides because their annual gross sales are too high. Some may consider this an incidental effect of an otherwise essential law; the farmers burdened by the added requirements, however, are unlikely to shrug their shoulders with similar apathy. Defining qualified farms and food processing facilities according to a national economic standard should not be expected to sufficiently provide enough flexibility for America’s diverse production methods.

## 2. *Polarization of the Playing Field*

Establishing the Tester Amendment exemption at \$500,000 may also have the effect of further polarizing the playing field, favoring small and large producers while ignoring those in the middle.<sup>165</sup> Some researchers argue

mid-sized farms are the most vulnerable in today’s polarized markets, since they are too small to compete in the highly consolidated commodity markets and too large and commoditized to sell in the direct markets.

Ironically, it is also the mid-sized farms that have a comparative advantage in producing unique, highly differentiated products. Their smaller size enables them to remain flexible and innovative enough to respond to highly differentiated markets.<sup>166</sup>

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162. HEWITT, MAKING SUPPER SAFE, *supra* note 10, at 59 (admitting, however, that raw milk litigation against small farmers has been the exception).

163. U.S. GEN. ACCOUNTING OFFICE, GAO/RCED-96-96, FOOD SAFETY: INFORMATION ON FOODBORNE ILLNESSES 6 (1996), available at <http://www.gao.gov/archive/1996/rc96096.pdf>.

164. Unfortunately, the study required in FSMA did little to aid understanding on this issue. 21 U.S.C. § 350g(l)(5) (Supp. V 2011).

165. See generally FRED KIRSCHENMANN ET AL., WHY WORRY ABOUT THE AGRICULTURE OF THE MIDDLE? (2008), <http://www.agofthemiddle.org/papers/whitepaper2.pdf> (arguing middle-sized farms are being squeezed out of agriculture).

166. *Id.* at 1–2.

Though the smallest qualifying farms will remain largely unaffected by polarization, small farms aspiring to grow into mid-sized farms might find their options limited or restrained if they find it necessary to stay within the qualifying criteria to maintain exempt status.<sup>167</sup> One of the growing challenges of the local food movement is providing enough *quantity* to effectively replace industrial food sources. Polarization of producers could dampen opportunities for middle-sized farmers to easily meet those challenges.

### C. Enforcement Challenges

#### 1. Lack of Adequate Resources

The Congressional Budget Office estimates implementation of FSMA will cost \$1.4 billion for the budget period between 2011 and 2015.<sup>168</sup> The law does not include mandatory appropriations but instead is dependent on discretionary appropriations subject to Congressional approval.<sup>169</sup> FDA notes, “Without additional funding, FDA will be challenged in implementing the legislation fully without compromising other key functions.”<sup>170</sup> FDA deputy commissioner for foods, Michael Taylor, suggested FDA had “already done a lot of work in anticipation of the new law” but went on to suggest funding will be a “continuing issue” as new resources are needed for implementation.<sup>171</sup> In fact, funding and slow rulemaking have stalled implementation of FSMA and some already contend “FDA is not being given adequate funding to do the job.”<sup>172</sup> To add to the problem, the Budget Control Act of 2011 mandated across the board spend-

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167. *See id.* at 1.

168. CONG. BUDGET OFFICE, COST ESTIMATE: S. 510, FOOD SAFETY MODERNIZATION ACT 10 (2010), available at <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/117xx/doc11794/s510.pdf>.

169. JOHNSON, FSMA, *supra* note 30, at 9.

170. *Food Safety Modernization Act (FSMA): Frequently Asked Questions*, *supra* note 41.

171. Helena Bottemiller, *FDA's Taylor: 'We'll Hit the Ground Running'*, FOOD SAFETY NEWS (Jan. 28, 2011), <http://www.foodsafetynews.com/2011/01/taylor-fda-will-hit-the-ground-running-to-implement-new-law/>.

172. U.S. PUB. INTEREST RESEARCH GRP., TOTAL FOOD RECALL: UNSAFE FOODS PUTTING AMERICAN LIVES AT RISK 4, 5 (2012), available at <http://www.uspirg.org/sites/pirg/files/reports/USP%20TotalFoodRecall%2010-24.pdf>.

ing cuts<sup>173</sup> that will affect FDA and likely cause further delays in rulemaking and less vigorous implementation of FSMA.<sup>174</sup>

Between 2004 and 2010, prior to FSMA, the number of domestic registered food facilities eligible for inspections by FDA increased from 121,534 to 252,433 (100% increase).<sup>175</sup> The number of food inspectors only increased from 2172 to 2516 (14% increase) in the same period.<sup>176</sup> Those numbers alone suggest FDA needs more resources to adequately do their job, but FSMA further expands the responsibilities of FDA, including a higher frequency of inspections at food facilities, among other mandates. The number of inspections conducted by FDA is projected to increase from the 7400 conducted in 2009 to an estimated 50,000 in 2015 to meet the new demands of FSMA.<sup>177</sup> Current inspection rates have traditionally averaged once every ten years.<sup>178</sup> Under FSMA, FDA is required to increase the inspection rate of qualifying facilities.<sup>179</sup> Domestic facilities inspections must occur once every three to five years depending upon the level of risk the facility poses.<sup>180</sup> To meet these elevated requirements, President Obama requested appropriations of \$955 million for food safety initiatives in his 2012 budget.<sup>181</sup> Instead of granting the increase, Congress responded with a proposed decrease to FDA's food budget by \$87 million, to a total of \$750 million.<sup>182</sup> To

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173. Budget Control Act of 2011, Pub. L. 112-25, 125 Stat. 240 (to be codified in scattered sections of the U.S.C.).

174. Helena Bottemiller, *Sequester Expected to Have Big Impact on Food Safety; Details Unknown*, FOOD SAFETY NEWS (Feb. 28, 2013), <http://www.foodsafetynews.com/2013/02/as-agencies-brace-for-sequester-few-details-on-impact-to-food-safety/>.

175. JOHNSON, FSMA, *supra* note 30, at 17 tbl.1.

176. *Id.*

177. 156 CONG. REC. S8226 (daily ed. Nov. 29, 2010) (statement of Sen. Dodd).

178. DEWAAL & PLUNKETT, *supra* note 4, at 4.

179. 21 U.S.C. § 350j(a)(2) (Supp. V 2011).

180. *Id.* § 350j(a)(2)(B) (high-risk-facilities); *id.* § 350j(a)(2)(C) (non-high-risk facilities).

181. Lyndsey Layton, *House Republicans Vote to Cut Funds to Implement Food Safety Law*, WASH. POST, June 16, 2011, [http://www.washingtonpost.com/politics/house-republicans-vote-to-cut-funds-to-implement-food-safety-law/2011/06/16/AGMS82XH\\_story.html](http://www.washingtonpost.com/politics/house-republicans-vote-to-cut-funds-to-implement-food-safety-law/2011/06/16/AGMS82XH_story.html) [hereinafter Layton, *Cut Funds*]. See OFFICE OF MGMT. & BUDGET, FISCAL YEAR 2013 BUDGET OF THE U.S. GOVERNMENT 113 (2012), available at <http://www.whitehouse.gov/sites/default/files/omb/budget/fy2013/assets/budget.pdf> (showing, within the President's overall budget, FDA's budget at 2.403 billion dollars in 2011, an estimated 2.506 billion in 2012, and an estimated 2.517 in 2013, not considering fees collected which, when accounted for, increase the percentage of gain in FDA's budget); Helena Bottemiller, *House Budget Seeks Steep Spending Cuts*, FOOD SAFETY NEWS (Mar. 21, 2012), <http://www.foodsafetynews.com/2012/03/house-budget-seeks-steep-spending-cuts/> (describing the proposed budget for 2013 by the House of Representatives, including significant spending cuts to the health and human services budget which would likely impact FDA).

182. 157 CONG. REC. H4253 (daily ed. June 15, 2011) (statement of Rep. Dingell); Layton, *Cut Funds*, *supra* note 181.

support his argument against increased funding for FSMA, Representative Kingston from Georgia calculated the U.S. food supply is 99.99% safe.<sup>183</sup> Under the 2013 budget proposed by the House Appropriations Subcommittee, FDA suffered a \$16.3 million cut despite requests for increased food safety funding.<sup>184</sup>

Whether due to a lack of resources or strategic political maneuvering during an election year, FDA failed to meet their statutory deadlines for significant components of FSMA.<sup>185</sup> After an eight month delay in rulemaking, the Center for Food Safety filed a lawsuit against FDA alleging an “abdication of the agency’s fundamental responsibilities” for failure to complete the required rules more quickly.<sup>186</sup> Four months later, the Office of Management and Budget finally released proposed rules for HARPC and produce safety standards one year after their due date.<sup>187</sup>

Without sufficient resources to fully realize the goals of FSMA, policing small farmers and processors would seem like a low priority in light of the hazards recognized, and in some instances realized, by the larger farms and processing facilities.<sup>188</sup> The HHS Secretary is required to “identify high-risk facilities and shall allocate resources to inspect facilities according to the known safety risks.”<sup>189</sup> With severely limited resources, the requirement to prioritize high-risk facilities may compete with the mandated periodic inspections of low-risk facilities that must occur every five years. “Almost all food safety experts agree on the need to concentrate finite resources on the highest-risk products, processes, and operations, and that the decisions on what these are must be based on authoritative information supported by sound science.”<sup>190</sup> If high-risk facilities receive focus, it may be business as usual for the many low-risk small farmers

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183. 157 CONG. REC. H4255 (daily ed. June 15, 2011) (statement of Rep. Kingston).

184. Press Release, House of Rep. Comm. on Appropriations, Appropriations Committee Releases the Fiscal Year 2013 Agriculture Appropriations Bill (June 5, 2012), available at <http://appropriations.house.gov/news/documentsingle.aspx?DocumentID=298229>.

185. Helena Bottemiller, *Obama Administration Sued for Delay of FSMA Implementation*, FOOD SAFETY NEWS (Aug. 31, 2012), <http://www.foodsafetynews.com/2012/08/obama-administration-sued-for-delay-on-fsma-implementation/>.

186. Complaint at 2–3, *Ctr. for Food Safety v. Hamburg*, No. 12-4529 (N.D. Cal., Aug. 29, 2012).

187. Press Release, U.S. Food & Drug Admin., FDA Proposes New Food Safety Standards on Foodborne Illness Prevention and Produce Safety (Jan. 4, 2013), available at <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm334156.htm>.

188. See, e.g., Layton, *Egg Farmers Face Questions*, *supra* note 20 (describing largest national *Salmonella* outbreak caused by one of the biggest egg producers in the country).

189. 21 U.S.C. § 350j(a)(1).

190. LISTER & BECKER, *supra* note 17, at 22.



and food facilities, at least until more resources are provided to FDA.<sup>191</sup> An FDA official admitted, ““We’re not going to be adequately resourced to inspect all the farms.””<sup>192</sup> Weak enforcement records will do little to inspire many farmers and food processors into strict compliance. If the mandates of FSMA go unenforced, regulations governing small farms and processors, especially those neglected, will only serve to provide consumers with a false sense of security and decrease their personal awareness. In this sense, enforcement of regulations placed on small entities not meeting an exemption is an overly ambitious, and possibly unattainable, objective considering practical budget limitations.

## 2. *Effectiveness of Regulations*

A USDA Economic Research Service report examining *Salmonella* content in meat and poultry examines and questions the effectiveness of process controls, like those relied upon by FSMA.<sup>193</sup> The study found “management-determined actions . . . account[ed] for about two-thirds and process regulations about one-third of reductions in *Salmonella* [] in meat and poultry.”<sup>194</sup> Management-determined actions included investments in labor, human and physical capital, food safety technologies, and organizational arrangements, such as contractual relationships that have the effect of enhancing food safety process controls.<sup>195</sup> An example of a contractual relationship includes a purchaser of the product requiring the processor to adhere to specific good practices to help ensure food safety (sometimes including special certification), often in exchange for a price premium, all in an effort to prevent illness outbreak and subsequent erosion of consumer confidence in their brand.<sup>196</sup> In contrast, process regulations include “cleaning and sanitation tasks . . . and monitoring tasks of critical plant operations that are included in a plant’s Hazard Analysis and Critical Control Point (HACCP) plan.”<sup>197</sup> FSMA focuses on process regulations by including HARPC requirements (similar to HACCP) and detailed prevention controls relat-

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191. See Global Food Solutions, *The Food Safety Modernization Act: The Proof is in the Budget*, LEAVITT PARTNERS BLOG (Feb. 17, 2011), <http://leavittpartnersblog.com/2011/02/the-food-safety-modernization-actthe-proof-is-in-the-budget/> (suggesting enforcement will be spotty because of budget limitations).

192. Mateusz Perkowski, *Farmers Question Costs of New Food Safety Regs*, CAPITAL PRESS, Apr. 3, 2013, <http://www.capitalpress.com/content/mp-FDA-meeting-032713>.

193. See MICHAEL OLLINGER & DANNA MOORE, ECON. RESEARCH SERV., USDA, ERR-75, *THE INTERPLAY OF REGULATION AND MARKET INCENTIVES IN PROVIDING FOOD SAFETY* (2009), available at [http://www.ers.usda.gov/media/156230/err75\\_1\\_1\\_.pdf](http://www.ers.usda.gov/media/156230/err75_1_1_.pdf).

194. *Id.* at 37.

195. *Id.* at 11.

196. *See id.* at 12.

197. *Id.* at 1.

ing to cleanliness and sanitation.<sup>198</sup> The authors of the report concluded the “results demonstrate that both process regulation and management-determined actions play vital roles in meat and poultry food safety process control.”<sup>199</sup> Though this is evidence from only one study, it raises questions as to whether efforts to achieve food safety that focus strictly on government regulation through process controls are less likely to provide the level of security desired and expected by legislators and consumers. Instead, accountability through management-determined actions appears to be a significant driver—causing companies to tread cautiously to avoid embarrassing media attention. FSMA arguably erodes accountability, as discussed below.<sup>200</sup>

The HARPC program is an important feature of FSMA and is similar to the HACCP program in the beef industry.<sup>201</sup> Like HARPC, HACCP focuses on prevention of food borne illness through strict handling standards, careful sanitation, and prevention plans in a type of industry self-regulation.<sup>202</sup> After implementation of the HACCP program, results failed to meet desired objectives and the CDC reports demonstrated “no real decline” in the rate of *E. coli*, *Campylobacter*, and *Listeria* illnesses in the mid-2000s.<sup>203</sup> The CDC reported incidences of certain foodborne illnesses decreased between 1996 and 2004, but have failed to decrease since then, and admitted “additional efforts are needed” to control specific pathogens like *E. coli* in cattle and prevent their spread.<sup>204</sup> Large recalls of meat due to *Salmonella* and *E. coli* contamination are still frequent occurrences.<sup>205</sup> Table 1 shows the number of *E. coli* and *Listeria* recalls each year since 1995, stemming from either foodborne illness outbreaks or contamina-

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198. See 21 U.S.C. § 350g (Supp. V 2011).

199. OLLINGER & MOORE, *supra* note 193, at 37.

200. See *infra* Part III.E.

201. See JOHNSON, FSMA, *supra* note 30, at 12.

202. Eileen Starbranch Pape, Comment, *A Flawed Inspection System: Improvements to Current USDA Inspection Practices Needed to Ensure Safer Beef Products*, 48 HOUS. L. REV. 421, 438 (2011); see 9 C.F.R. §§ 417.1–8 (2012).

203. *Hearing to Review Current Food Safety Systems: Hearing Before the H. Comm. on Agric.*, 111th Cong. 50–51 (2009) (statement of Hon. Carol L. Tucker-Foreman, Distinguished Fellow, Food Policy Inst., Consumer Fed’n of Am.); Ctrs. for Disease Control & Prevention, *Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly Through Food – 10 States, 2007*, 57 MORBIDITY & MORTALITY WEEKLY REP. 366, 368 (2008) [hereinafter *2007 Preliminary FoodNet Data*], available at <http://www.cdc.gov/mmwr/PDF/wk/mm5714.pdf> (finding no statistically significant decrease in foodborne illness).

204. *2007 Preliminary FoodNet Data*, *supra* note 203, at 369.

205. GEOFFREY S. BECKER, CONG. RESEARCH SERV., RL32922, MEAT AND POULTRY INSPECTIONS: BACKGROUND AND SELECTED ISSUES 9 (2010) [hereinafter BECKER, MEAT AND POULTRY INSPECTIONS]. See generally *Recall Case Archive*, FOOD SAFETY & INSPECTION SERV., USDA, [http://www.fsis.usda.gov/Fsis\\_Recalls/Recall\\_Case\\_Archive/index.asp](http://www.fsis.usda.gov/Fsis_Recalls/Recall_Case_Archive/index.asp) (last visited Apr. 12, 2013) (providing summaries of food safety recalls by year, product, and reason for recall).

tion discovered during routine testing by the Food Safety and Inspection Service (FSIS).

Table 1. *E coli* and *Listeria* Recall Incidences<sup>206</sup>

	2012	2011	2010	2009	2008	2007	2006	2005	2004
<i>E coli</i>	4	13	12	16	17	22	8	5	7
<i>Listeria</i>	16	11	8	8	15	11	6	30	14
	2003	2002	2001	2000	1999	1998	1997	1996	1995
<i>E coli</i>	11	34	29	21	10	13	6	2	5
<i>Listeria</i>	15	39	25	35	31	6	3	6	11

Some are not surprised, and argue “[t]he current HACCP system hampers inspection effectiveness”<sup>207</sup> and leaves gaps in the current food safety system.<sup>208</sup> HACCP relies on industry initiative, allowing business to create and manage facility specific contamination prevention plans with government verification that the appropriate procedures are followed.<sup>209</sup> Many describe the program as the proverbial “fox guarding the henhouse” due to the conflict between profits in the form of processing efficiency and food safety practices.<sup>210</sup> Most revealing, a poll of FSIS meat inspectors revealed that 344 out of 426 responding “felt they cannot generally enforce the law as well under HACCP as before

206. *Recall Case Archive*, *supra* note 205. This data only shows the frequency of voluntary recalls, many of which resulted in little or no recalled meat actually being recaptured, and does not depict the incidence of foodborne illness. *Id.*

207. Pape, *supra* note 202, at 438.

208. *2008 Preliminary FoodNet Data*, *supra* note 8, at 336.

209. See 9 C.F.R. §§ 417.1–.8 (2012) (outlining HACCP requirements for industry that rely primarily on industry initiative and occasional government oversight).

210. HEWITT, MAKING SUPPER SAFE, *supra* note 10, at 25; MARION NESTLE, SAFE FOOD: BACTERIA, BIOTECHNOLOGY, AND BIOTERRORISM 86 (2003).

HACCP.”<sup>211</sup> Out of 338 respondents, 266 thought the “primary reason they cannot enforce the law as ‘realistically’ under HACCP is because government inspection tasks are reduced, since government monitoring points are now based on company-created HACCP plans.”<sup>212</sup> Though a HACCP program offers promise on paper and when implemented and executed thoughtfully and carefully,<sup>213</sup> the lack of clear success should caution policy makers attempting to emulate the program in other food sectors.

#### D. *Taking Options off the Table*

##### 1. *Collaborative Marketing*

The requirements of the Tester Amendment effectively prohibit collaborative marketing as a primary market outlet for small farmers and food processors. To meet the Tester exemption for the produce safety standards, farmers cannot send more than fifty percent of their product to users who do not fit the definition of a qualified end user.<sup>214</sup> Qualified end users include the direct consumer, restaurant, or retail food establishment, which includes farmers’ markets, roadside stands, and CSAs.<sup>215</sup> Under this definition, a local or regional food distributor or wholesaler buying produce for subsequent sale would not be considered a qualified end user.<sup>216</sup> Prior to FSMA, a group of farmers uninterested in marketing their own product in local communities could combine their efforts and sell to a local distributor who does have the time, resources, and relationships to effectively market the product to regional consumers. These models are beginning to grow as local foods become more available, farmers recognize the advantages of pooling resources, and local food-hungry institutions desire to work with larger distributors rather than multiple individual farmers.<sup>217</sup> On a local scale these networks still share a high degree of accountability, in-line with the purpose of the Tester exemption. To some farmers, outside distributors are important ingredients to the farm’s success, as it allows the farmer to spend more

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211. FELICIA NESTOR & WENONAH HAUTER, GOV’T ACCOUNTABILITY PROJECT & PUBLIC CITIZEN, *THE JUNGLE 2000: IS AMERICA’S MEAT FIT TO EAT?* 2, 4 (2000).

212. *Id.* at 5.

213. *See id.* at 6.

214. 21 U.S.C. §§ 350g(l)(1)(C)(ii)(I), 350h(f)(1)(A) (Supp. V 2011).

215. *Id.* § 350g(l)(4)(B)–(C); Pub. L. 111-353, § 350d(c)(1), 124 Stat. 3885 (2011) (codified at 21 U.S.C. 350d note); *see also* 21 C.F.R. § 1.227(b)(11) (2012).

216. *What Do the New Laws Mean*, *supra* note 137, at 1.

217. Greg Lawless et al., *The Farmer-Food Buyer Dialogue Project: The Local Farm Sector* (Univ. of Wis.-Madison Ctr. for Coops., UWCC Occasional Paper No. 13, 1999), available at <http://www.uwcc.wisc.edu/info/ffbuyer/text2.html#2>.

time managing the farm rather than marketing.<sup>218</sup> For farmers to take full advantage of collaborative marketing opportunities, they will forgo exempt status under the Tester Amendment and become subjected to regulatory opportunity costs, which may deter this sort of beneficial relationship and hamper the success of local foods. The lack of regional and local food distribution systems is one of the most significant barriers to local food market development and the Tester Amendment further inhibits the prospect of successful collaboration among regional farmers.<sup>219</sup>

## 2. Value Added

FSMA requires that food processors grossing over \$500,000 comply with HARPC requirements.<sup>220</sup> Traditionally, food safety regulations do not classify farms as food facilities for regulatory purposes.<sup>221</sup> If a farm adds value, however, to any of their produce consumed off the farm, they may become classified as a food facility and fall subject to the HARPC requirements.<sup>222</sup> Value-added processes commonly include many of the actions that are defined as manufacturing or processing, including cooking, processing, combining, churning, culturing, grinding, hulling, extracting, drying, smoking, packaging, and labeling.<sup>223</sup> The added burdens associated with FSMA regulations detract from benefits provided by value-added activities. This subtle distinction further limits their opportunities for economic growth, as value added products offer tremendous opportunities for small farmers to increase their economic return on their small acreages, and value added processes are an essential ingredient in the economic success of many small operations.<sup>224</sup>

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218. STEVE MARTINEZ ET AL., ECON. RESEARCH SERV., USDA, REPORT NO. 97, LOCAL FOOD SYSTEMS: CONCEPTS, IMPACTS, AND ISSUES 24–25 (2010), available at [http://www.ers.usda.gov/media/122868/err97\\_1\\_1.pdf](http://www.ers.usda.gov/media/122868/err97_1_1.pdf).

219. LINDSEY DAY-FARNSWORTH ET AL., UNIV. OF WIS-EXTENSION AGRIC. INNOVATION CTR., UNIV. OF WIS.-MADISON CTR. FOR INTEGRATED AGRIC. SYS., SCALING UP: MEETING THE DEMAND FOR LOCAL FOOD, at i (2009).

220. See 21 U.S.C. § 350g(l)(1)(C)(ii)(II) (Supp. V 2011).

221. *Id.* § 350d(c)(1); see also MacDonald & McGearry, *supra* note 80, at 3 (noting the definition of facility now includes farms if they process the crops they grow).

222. 21 C.F.R. § 1.227(b)(2), (6) (2012) (defining facility as an establishment that manufactures or processes food for consumption).

223. *Id.* § 1.227(b)(6); see also HOLLY BORN & JANET BACHMANN, NAT'L CTR. FOR APPROPRIATE TECH., ADDING VALUE TO FARM PRODUCTS: AN OVERVIEW 1 (2006), available at <http://www.sdhdidaho.org/env/pdf/valueadded.pdf>.

224. JOEL SALATIN, YOU CAN FARM: THE ENTREPRENEUR'S GUIDE TO START AND SUCCEED IN A FARMING ENTERPRISE 434 (1998); MARTINEZ ET AL., *supra* note 218, at 23.

E. *Shared Accountability*

Stepping back to examine the effects of FSMA as a whole, U.S. food supplies may actually become less safe due to removal of direct accountability from consumers to producers under FSMA. The HARPC approach, like HACCP in the meat industry, “emphasizes that the food industry bears primary responsibility for producing safe food and ties the industry’s system for producing safe food to the government’s system of regulatory supervision.”<sup>225</sup> Salatin criticizes the government’s gatekeeping role in this type of regulatory regime, asking “[w]hat is the first thing said by the CEO of a company embroiled in a nationwide food recall? . . . ‘We’ve complied with every government food safety requirement.’”<sup>226</sup> He further argues, “If we didn’t have the government involved, then the business would be forced to accept liability. As soon as the business is forced to accept liability, it will become much more careful about how it handles things.”<sup>227</sup> Salatin contends that the government’s stepped-up role as watchdog gives industry a convenient excuse where none existed before.<sup>228</sup> With multiple actors involved, finger-pointing between government and industry officials is likely to follow future foodborne illness outbreaks. Efforts to increase transparency and accountability in the food system should be the keystone to any food safety legislation. FSMA omits provisions that would increase accountability and, in fact, further clouds the line of sight from producer to consumer with the growing shadow of government involvement.<sup>229</sup>

Leading up to the passage of FSMA, many in the industry stepped forward to support the new legislation despite the inevitable costs that would result.<sup>230</sup> Inspiring this pro-regulatory position held by the food industry is the fear

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225. *FDA Food Safety Modernization Act: Law, Explanation, and Analysis*, CCH IntelliConnect ¶ 120.

226. SALATIN, THIS AIN’T NORMAL, *supra* note 85, at 339; *see, e.g.*, NESTLE, *supra* note 210, at 73 (meatpacker stating the company complied with federal regulations); Lyndsey Layton, *Latest Food Recall One of Largest Ever*, SEATTLE TIMES, Jan. 29, 2009, [http://seattletimes.com/html/nationworld/2008683232\\_peanut29.html?syndication=rss](http://seattletimes.com/html/nationworld/2008683232_peanut29.html?syndication=rss). After an illness outbreak in peanuts, a spokesman for Peanut Corp. of America “said the company complied with all requests by regulators from ‘day one.’” *Id.*

227. SALATIN, THIS AIN’T NORMAL, *supra* note 85, at 302.

228. *See id.*

229. *See* HEWITT, MAKING SUPPER SAFE, *supra* note 10, at 253–54 (suggesting FSMA would “further the trend toward consolidation and opaqueness” in the food industry).

230. Taryn Luntz, *Industry Gets Behind Tougher Regulations*, E&E DAILY (Mar. 20, 2009), <http://www.eenews.net/public/EEDaily/2009/03/20/11>. David Mackay, CEO of Kellogg Co. stated, “I think anything we can do to strengthen confidence in the food safety system in the U.S. is worth doing.” *Id.*; *see also* Letter from Am. Feed Indus. Ass’n et al. to Sen. Harkin & Sen. Enzi, *supra* note 29 (letter from thirty industry groups supporting FSMA).

of significant losses in profits should outbreaks continue with such frequency and severity. The economic fall-out after the 2006 spinach *E. coli* outbreak from a California farm resulted in a \$60.6 million net loss in leafy greens expenditures in the fifteen months following the outbreak.<sup>231</sup> Worse yet for industry producers, is many consumers continued to buy spinach, but instead purchased it from local growers. One grower in Vermont expected the outbreak to hurt his farm's sales, but instead he sold double the usual amount of spinach immediately after the outbreak.<sup>232</sup> In 2011, the year of the cantaloupe illness outbreak, it was reported that sixty-one percent of respondents changed their food habits as a result of the food news coverage.<sup>233</sup> Though supportive of the original language of FSMA, industry quickly denounced inclusion of the Tester Amendment and the "loopholes" it provides small farmers and processors, arguing it would undermine consumer confidence.<sup>234</sup>

An ambitious regulatory scheme like FSMA creates the risk that accountability becomes shared amongst multiple parties, both industry and government, and the incentive for industry to take on full responsibility to protect customers diminishes. In contrast, the direct relationship between small farmers and consumers provides clear incentive and accountability. In the long run, legislation that threatens the existence of small producers could have the unintended effect of decreasing the safety of the food supply if direct accountability is replaced by governmental oversight *and* regulators are unable to effectively decrease illness outbreaks.

#### F. *Whose Science Do We Use?*

FSMA requires FDA utilize "science-based" methods to study and determine risks and when drafting rules and guidance for the implementation of a

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231. Carlos Arnade et al., *Consumers' Response to the 2006 Foodborne Illness Outbreak Linked to Spinach*, 8 AMBER WAVES 34, 40, Dec. 2010, available at <https://www.hsdl.org/?view&did=24537> (demonstrating that consumers do respond to product contamination information).

232. Byczynski, *supra* note 121.

233. Press Release, MarketWire, Food Safety Eclipses Rising Food Cost as Top Food Story of 2011 (Dec. 8, 2011), <http://www.marketwire.com/press-release/food-safety-eclipses-rising-food-costs-as-top-food-story-of-2011-1596686.htm>.

234. See, e.g., 156 CONG. REC. S8225 (daily ed. Nov. 29, 2010) (statement of Sen. Chambliss); see also Helena Bottemiller, *Q&A: Why the Produce Industry Opposes Tester*, FOOD SAFETY NEWS (Nov. 23, 2010), <http://www.foodsafetynews.com/2010/11/qa-why-the-produce-industry-opposes-tester-on-food-safety/> (quoting Bob Whitaker, Chief Science Officer of the Produce Marketing Association: "We were disappointed last week when the Tester amendment basically stayed intact and made exemptions possible.").



HARPC program and produce safety standards.<sup>235</sup> Scientific principles are not entirely new to food safety.<sup>236</sup> They provided the basis for good agricultural practices (the previous industry standard for food safety), good hygiene practices, manufacturing practices, and the HACCP program.<sup>237</sup> Other examples of science-based activities include “[e]stablishing acceptable daily intake for chemical additives in food,” “[e]stablishing product safety standards,” and “[u]sing risk assessment to support food safety regulations and other decision making.”<sup>238</sup> Salatin, recognizing science can mean different things to different people, asks, “Whose science will it be?”<sup>239</sup> Skeptically, he suggests the regulations will be founded on lab science supported by the industry rather than traditional wisdom and practices followed by many small farmers.<sup>240</sup>

Use of the traditional brand of laboratory, science-based principles to determine the appropriate regulations and methods of risk assessment have weaknesses. Scientific knowledge changes constantly as time passes and more observations are made, and this change occurs at a much quicker rate than national legislation.<sup>241</sup> Furthermore, scientific results often yield disagreement between scientists when interpreting their meaning.<sup>242</sup> With such divergent views of “science,” constructing a set of guidelines that meet the objectives and values of both industrial and small farmers presents a formidable challenge. Further, unlike small farms and processing facilities, industrial farms and facilities are less nimble and able to adapt. Therefore, science based principles catering to large farms or facilities may not provide the agility necessary to benefit small farms and facilities.

### G. *Discretion Provides Uncertainty*

Much of the opposition to FSMA, as originally written without the Tester Amendment, concerned the uncertainty written into the law where FDA was granted discretion to define the size of exempt farms and facilities and the bene-

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235. See, e.g., 21 U.S.C. §§ 350g(n)(1)(A), 350h(a)(1)(A), (3)(B), 2201(b) (Supp. V 2011).

236. NAT’L RESEARCH COUNCIL, FOOD SAFETY AND FOODBORNE DISEASE SURVEILLANCE SYSTEMS: PROCEEDINGS OF AN IRANIAN-AMERICAN WORKSHOP 80 (Glenn Schweitzer et al. eds., 2006).

237. *Id.*

238. *Id.* at box 1.

239. SALATIN, THIS AIN’T NORMAL, *supra* note 85, at 342.

240. *Id.*

241. MICKEY PARISH, CONG. RESEARCH SERV., RS20310, SCIENCE BEHIND THE REGULATION OF FOOD SAFETY: RISK ASSESSMENT AND THE PRECAUTIONARY PRINCIPLE (1999).

242. *Id.*

fits they might receive under the exemption.<sup>243</sup> Under FSMA, FDA is instructed to provide “sufficient flexibility to be applicable to various types of entities engaged in the production and harvesting of fruits and vegetables.”<sup>244</sup> This language concerned small farmers and processors who were skeptical FDA would effectively support their interests and needs during rulemaking without specific protections.<sup>245</sup> With inclusion of the Tester Amendment, some of this uncertainty disappeared. Despite the guaranteed protections of the Tester Amendment, many elements of the law affecting small farmers and processors still remain up to FDA’s discretion.<sup>246</sup> In the proposed rules FDA *declined to use their discretionary authority* to exempt classified small and very small businesses (those selling between \$25,000 and \$500,000 of food) from the produce safety standards,<sup>247</sup> justifying the decision by arguing low risk produce is exempted for *everyone* and an exemption was already proposed for the smallest of farms.<sup>248</sup> The rules propose exempting farms with an average annual monetary value of food sold during the previous three year period of less than \$25,000 from the produce safety standards.<sup>249</sup> We can only guess what the rules would have looked like without inclusion of the Tester Amendment, but this indication suggests all farmers earning more than \$25,000 on average, a very low cut-off for this type of exemption, would have been out-of-luck and required to comply with the produce safety regulations without any guaranteed protections.

The uncertainties that plague the food system from farm to purchaser can have a chilling effect and work to inhibit the growth of local food production and sales.<sup>250</sup> Government agencies are given a large degree of deference by the courts when their decisions are challenged.<sup>251</sup> Agency interpretation of ambiguous

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243. See, e.g., MacDonald & McGeary, *supra* note 80, at 2.

244. 21 U.S.C. § 350h(a)(3)(A) (Supp. V 2011).

245. See MacDonald & McGeary, *supra* note 80, at 2 (noting lack of enforceable protections).

246. See, e.g., 21 U.S.C. § 350g(n) (allowing FDA to establish science-based standards and define small and very small business); see also 78 Fed. Reg. 3504 (proposed Jan. 16, 2013) (to be codified in scattered sections of 21 C.F.R.) (proposed produce standards); 78 Fed. Reg. 3646 (proposed Jan. 16, 2013) (to be codified in scattered sections of 21 C.F.R.) (proposed HARPC regulations).

247. 78 Fed. Reg. at 3618; see also 21 U.S.C. § 350h(a)(1)(B).

248. 78 Fed. Reg. at 3618; see also *id.* at 3630 (to be codified at 21 C.F.R. § 112.2); *id.* at 3632 (to be codified at 21 C.F.R. § 112.4).

249. *Id.* at 3632.

250. MARTINEZ ET AL., *supra* note 218, at 27–28; see DEBRA TROPP & JIM BARHAM, AGRIC. MKTG. SERV., USDA, NATIONAL FARMERS MARKET SUMMIT PROCEEDINGS REPORT 18–19 (2008), available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5066926>.

251. See *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843–45 (1984).

statutory language will often be upheld as long as is not arbitrary and capricious and rests within the confines of permissible construction of the statute.<sup>252</sup>

FDA regulatory authority extends to activities on the farm under the Federal Food, Drug, and Cosmetic Act (FFDCA),<sup>253</sup> Public Health Services Act (PHSA),<sup>254</sup> and now under the FSMA provisions added to the FFDCA.<sup>255</sup> Courts have interpreted the power granted under the FFDCA and PHSA in a broad manner, particularly when public health is at issue.<sup>256</sup> Arguing in favor of aggressive food safety measures to save lives is a powerful argument. If FDA follows a similar philosophy under FSMA, small farmers and food processors may still be burdened with onerous requirements or find their exemptions difficult to prove if FDA feels public pressure to use their rulemaking and enforcement authority broadly and forcefully. Perhaps more of a threat, FDA retains the authority to withdraw exemptions if an illness outbreak is directly linked to a qualifying farm or food facility or FDA determines removal of the exemption is “necessary to protect the public health and prevent or mitigate a foodborne illness outbreak.”<sup>257</sup> One can imagine the differences in opinion that might result between a farmer or processor and FDA over when something is “necessary to protect the public health,” particularly if FDA grossly errs on the side of caution when they perceive a threat and unnecessarily strip a farmer of their statutory protections. With

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252. *Id.*

253. Neither the FDCA nor the PHSA grant explicit authority to regulate on-the-farm activity, however, some of the more general provisions have been interpreted to allow such. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(b) (2006 & Supp. V 2011) (prohibiting adulterated or misbranded foods from entering interstate commerce); 21 U.S.C. § 342(a)(1) (deeming a food adulterated if it “bears or contains any poisonous or deleterious substance which may render it injurious to health”); *see, e.g.*, U.S. v. Organic Pastures Dairy Co., 708 F. Supp. 2d 1005 (E.D. Cal 2010) (describing action against a farm for distributing raw milk in interstate commerce brought under the FDCA and the PHSA).

254. Public Health Service Act, 42 U.S.C. § 264(a) (2006) (authorizing surgeon general to enforce regulations “to prevent introduction, transmission, or spread of communicable diseases”).

255. FSMA contains explicit authority for on-the-farm regulations. *See, e.g.*, 21 U.S.C. § 350h; *see also* VANESSA K. BURROWS, CONG. RESEARCH SERV., RS22939, FDA AUTHORITY TO REGULATE ON-FARM ACTIVITY 3 (2008).

256. BURROWS, *supra* note 255, at 4; *see, e.g.*, Nutraceutical Corp. v. Von Eschenbach, 459 F.3d 1033, 1039 (10th Cir. 2006) (“[The FFDCA] should not be read too restrictively but in manner consistent with the statute’s overriding purpose to protect public health.”); United States v. N.S. Food Prods. Corp., 568 F.2d 240, 246 (2d Cir. 1977) (citing United States v. Midwest Video Corp., 406 U.S. 649 (1972)) (“When agency rulemaking serves the purposes of the statute, courts should refuse to adopt a narrow construction of the enabling legislation which would undercut the agency’s authority to promulgate such rules.”).

257. 78 Fed. Reg. 3646, 3776 (proposed Jan. 16, 2013) (to be codified at 21 C.F.R. § 117.5(a)–(b)); 78 Fed. Reg. 3504, 3611 (proposed Jan. 16, 2013) (to be codified at 21 C.F.R. § 112.201).

the negative publicity and heavy-handed enforcement actions surrounding raw milk sales, it is understandable why some small farmers fear government involvement in on-the-farm activities and local sales.<sup>258</sup>

FSMA leaves certain decisions to the discretion of FDA largely because the data on farms, food processors, and causes of illness are incomplete.<sup>259</sup> The detailed effects FSMA will have on farmers across America was speculative during the hearing debates, yet the legislature went ahead and enacted law anyway.<sup>260</sup> Despite public pressure for fast action and results, prudence would suggest conducting a study and legislating *after* the subjects of regulation and the scope of the problems at issue were identified and accurately characterized.

#### IV. ALTERNATIVES TO FSMA REGULATORY APPROACH

Broad and pervasive federal food safety regulations, with or without exemptions for small farms and food processors, are not the only way to work toward a safer food supply. A variety of tactics exist to achieve a better food safety record that could be employed to encourage, rather than threaten, deter, or inhibit, the growth and success of localized food production on small farms and in food facilities without the need for clumsy and imperfect exceptions like the Tester Amendment.

##### A. *Burden Shifting*

FSMA takes a broad approach to food safety by passing regulations that have potential to affect the entire spectrum of farms and food processors under the jurisdiction of FDA. With the Tester Amendment, smaller farms meeting specific criteria are then granted exemptions from some of the more onerous requirements.<sup>261</sup> Especially considering FDA's limited resources discussed in Part III.C.1, regulations should instead cut straight to the heart of the problem and focus on the most significant threats to food safety. Rather than broad regulations affecting everyone, targeted regulations on the practices that are known or highly suspected to lead to wide-scale foodborne illness outbreaks would be

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258. See generally DAVID E. GUMPERT, *THE RAW MILK REVOLUTION: BEHIND AMERICA'S EMERGING BATTLE OVER FOOD RIGHTS* 1–16 (2009) (describing government pressure exerted on various raw milk dairies around the country).

259. See, e.g., 21 U.S.C. § 350g(n) (Supp. V 2011) (allowing FDA to establish science-based standards and define small and very small business using the results of the study required under section 350g(l)(5)); see also MUTH ET AL., *supra* note 153 (study results).

260. 156 CONG. REC. S8225 (daily ed. Nov. 29, 2010) (statement of Sen. Chambliss) (urging the Senate to wait until full impact is known before moving on the bill).

261. 21 U.S.C. §§ 350g(l), 350h(f).

more efficient. This approach would shift the regulatory burden to the most risky enterprises rather than requiring small producers to navigate further regulations and prove their exemption if their threat to food safety is negligible.

Which size and style of agricultural producers pose the greatest threat to food safety is still a debated issue. Comprehensive studies on the matter have not been conducted.<sup>262</sup> The significant increase in foodborne illness, paralleling the growth of modern animal production and processing where large volumes of animals are exposed to the same pathogens through close contact, however, seems more than coincidental.<sup>263</sup> *Campylobacter jejuni*, *Salmonella*, *E. coli*, and *Listeria* are among the most common foodborne illness pathogens.<sup>264</sup> The CDC reports that *Salmonella* isolates increased from six percent in 1980 to twenty-five percent in 1995.<sup>265</sup> *Campylobacter jejuni* emerged as a recognized foodborne pathogen in the late 1970s, *Listeria* in the early 1980s and *E. coli* in 1982.<sup>266</sup> Close contact between animals “favors the spread of pathogens,”<sup>267</sup> and therefore deserves some of the responsibility for increased bacteria levels.<sup>268</sup> Fruits and vegetables are often “contaminated by these pathogens through exposure to tainted fertilizers and sewage sludge.”<sup>269</sup>

Major incidences of foodborne illness outbreaks in the past decade all come from industrialized farms or processing facilities utilizing industrial methods.<sup>270</sup> Even the California spinach contamination, which some contend happened on a “small farm,”<sup>271</sup> was reported to be part of a larger ranching operation that maintained livestock and exported food across the country.<sup>272</sup> Rather than regulating everyone and granting exceptions in an era of tight resources,<sup>273</sup> regulations should set eligibility criteria that target the most high-risk farms and food processors, and allow for regulation of smaller farms and processors only if they

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262. The study required under the FSMA did not explore the root causes of foodborne illness. See MUTH ET AL., *supra* note 153.

263. S.F. Altekruse et al., *Emerging Foodborne Diseases*, 3 EMERGING INFECTIOUS DISEASES 285, 286 (1997), available at [ftp://ftp.cdc.gov/pub/EID/vol3no3/pdf/cohen.pdf](http://ftp.cdc.gov/pub/EID/vol3no3/pdf/cohen.pdf) (citing doubling of salmonellosis incidences accompanied by modern increases in centralized production).

264. See Altekruse et al., *supra* note 263, at 286–87.

265. *Id.* at 286.

266. *Id.* at 287.

267. NESTLE, *supra* note 210, at 45.

268. Andrew Kimbrell, *Myth Two: Industrial Food Is Safe, Healthy, and Nutritious*, in THE FATAL HARVEST READER: THE TRAGEDY OF INDUSTRIAL AGRICULTURE 12 (Andrew Kimbrell ed., 2002).

269. *Id.*

270. See discussion *supra* Part I.

271. See Ferguson, *supra* note 159.

272. LISTER & BECKER, *supra* note 17, at 21.

273. See discussion *supra* Part III.C.1 (discussing FDA budget).

exhibit clearly identified high risk factors in their farming or processing practices.

### B. Local Solutions

A second alternative includes reliance upon local or regional regulations that strike a balance between government regulations and local flexibility to govern food safety. To various degrees states have adopted food safety statutes and regulations of their own.<sup>274</sup> States are allowed to go beyond federal regulations as long as state laws are not inconsistent with federal law.<sup>275</sup> When a farm or food processor meets the Tester exemption, that farm or facility is still subject to enacted state laws with which it must comply.<sup>276</sup> Farmers and food processors meeting the Tester exemption in states without relevant food safety laws are required to conduct a HARPC-like program.<sup>277</sup> Under either scenario, small farms and food processors face some level of regulations or requirements, whether federal or state. Bringing the state laws into effect through FSMA is an unnecessary extra step. Instead, deference should be given to states for choosing when and how to regulate the growing and selling of produce from the beginning. Salatin suggests we “[p]ass federal legislation allowing community-based prototypes for intrajurisdictional commerce.”<sup>278</sup> Under such a scheme, “if [one] county wants to try a local food commerce prototype, allowing anyone to buy anything from anyone within the confines of our county, it should be free to do so.”<sup>279</sup> A few small towns in Maine did exactly that when they proposed a local food ordinance that rejected state and federal regulation of their local commerce.<sup>280</sup> One need not

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274. *Food Code Adoption by Population*, ASS’N OF FOOD & DRUG OFFICIALS, <http://www.afdo.org/Default.aspx?pageId=1417773> (last updated Sept. 17, 2012) (indicating that all fifty states have codified food regulations patterned after FDA’s model code).

275. NAT’L ASS’N OF STATE DEP’TS OF AGRIC. RESEARCH FOUND., *FOOD SAFETY: STATE AND FEDERAL STANDARDS AND REGULATIONS* 38 (1999).

276. 21 U.S.C. § 350g(l)(2)(B)(i)(II) (Supp. V 2011).

277. *See id.* § 350g(l)(2)(B)(i)(I).

278. SALATIN, *THIS AIN’T NORMAL*, *supra* note 85, at 346.

279. *Id.* at 346–47.

280. Rich Hewitt, *Farmers Seek to Protect Locally Grown Foods*, BANGOR DAILY NEWS, Feb. 24, 2011, <http://bangordailynews.com/2011/02/24/news/hancock/farmers-seek-to-protect-locally-grown-foods/>. Four of the five towns in Maine proposing a local food ordinance successfully passed the ordinance. Rebekah Wilce, *Local Food Ordinances from Maine to California*, PRWATCH (Oct. 10, 2011), <http://www.prwatch.org/news/2011/10/11034/local-food-ordinances-maine-california>; *see, e.g.*, BLUE HILL, ME., LOCAL FOOD AND COMMUNITY SELF-GOVERNANCE ORDINANCE OF 2011 (Apr. 1, 2011). Immediately after enactment, the state sent Blue Hill, Maine a letter warning they are still subject to state regulations. Letter from Walter E. Whitcomb, Commissioner of Agric., to Town of Blue Hill (Apr. 6, 2011), *available at* <http://www.bluehillme.com>.



completely dodge all government oversight as those in Maine are attempting to do, as those approaches have their own risks. But practical, regionalized regulations and oversight based on national uniform standards present a chance of being more flexible and adaptive to local needs, farms, and economies. If more adaptive, these approaches will likely be more successful at both securing food safety and serving the needs of small farmers and food processors.

Related to local control, USDA relies upon state inspection of approximately 1700 meat-processing facilities in twenty-seven states.<sup>281</sup> At a Senate committee hearing the director of the Ohio Department of Agriculture reported, “[State] personnel are generally more accessible and more flexible in providing inspection resources that are geared to the needs and timing of small plants . . .” and that states offer practical information, technical assistance, and are more adept at working with smaller plants “that cannot afford to employ a scientific staff or attorney to sort through all the regulations in searching for answers.”<sup>282</sup> Similar arguments could apply to state regulation and oversight of produce. Other drawbacks to federal regulations include the expense of meeting federal requirements unrelated to food safety, overtime expenses for services of federal regulators, and more challenging communication between farms, facilities, and federal regulatory agencies.<sup>283</sup> A survey among states that maintain a state inspection system for meat cited a ““desire for greater responsiveness to the unique needs of producers and processors”” as their reason for maintaining their state inspection programs.<sup>284</sup> These examples support the argument that local oversight is more efficient and flexible than federal governance on matters related to food. Of course local oversight maintains drawbacks, such as a lack of consistency between states, the fear that state standards will be more lax, and the fact that special interests might influence individual states.<sup>285</sup> Despite being state

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govoffice2.com/. Shortly thereafter, the state of Maine filed a lawsuit against a farmer selling unpasteurized milk without a state permit under the guise of the new local ordinance. Kevin Miller, *State Sues Blue Hill Farmer for Selling Unpasteurized Milk at Farmers' Markets*, BANGOR DAILY NEWS, Nov. 16, 2011, <http://bangordailynews.com/2011/11/16/news/hancock/blue-hill-farmer-cited-for-violating-state-law/>.

281. 2013 *Explanatory Notes*, FOOD SAFETY & INSPECTION SERV., USDA, 21-31 (2013), [http://www.fsis.usda.gov/PDF/FY2013\\_Budget\\_Explanatory\\_Notes.pdf](http://www.fsis.usda.gov/PDF/FY2013_Budget_Explanatory_Notes.pdf).

282. *Interstate Shipment of State-Inspected Meat and Poultry: Hearing Before the S. Comm. on Agric., Nutrition, and Forestry*, 106th Cong. 23–24 (2000) (statement of Fred L. Dailey, Dir., Ohio Dep't of Agric. and President, Nat'l Ass'n of State Dep'ts of Agric.).

283. *See id.* at 35–36 (statements of Patrick Boyle, President and CEO, Am. Meat Inst.).

284. KARA SLAUGHTER ET AL., UNIV. OF NEB. PUB. POL'Y CTR., POTENTIAL IMPACTS OF STATE MEAT AND POULTRY INSPECTION FOR THE STATE OF NEBRASKA 21 (2001), *available at* <http://ppc.unl.edu/userfiles/file/Documents/projects/StateMeatInspection/PotentialImpacts.pdf>.

285. GEOFFREY S. BECKER, CONG. RESEARCH SERV., RL34202, STATE-INSPECTED MEAT AND POULTRY: ISSUES FOR CONGRESS 8 (2008).



controlled, state inspected meat-processing plants are still expected to meet a federal baseline, which aids in consistency and quality assurance.<sup>286</sup> Similar baseline criteria or uniform performance standards could be set by the federal government for produce, giving states flexibility in how they achieve those criteria and in defining which farms and facilities are most deserving of close scrutiny and different levels of regulatory oversight. If jurisdictions fail to rise to this new charge, then federal intervention is justifiable. Given the enormous challenge in using federal oversight to adequately regulate and police a widely dispersed and diverse food production system,<sup>287</sup> the benefits of state regulation or another form of regional regulation are deserving of a second look. A program where states are given the role as the primary regulators and enforcers in the produce sector, with minimum standards set by the federal government, could alleviate the need for expensive, pervasive, and inflexible federal oversight like FSMA.

### C. Performance Standards

Another alternative to the regulatory scheme of FSMA includes the enforcement of performance standards. As a farmer, Joel Salatin suggests, “Just tell me where the finish line is, and I’ll figure out the best way to get there.”<sup>288</sup> People like Salatin contend that a less burdensome way of achieving food safety is to set reasonable food safety goals and allow farmers and producers the freedom and flexibility to operate their farm or business in any manner as long as they can achieve those goals.<sup>289</sup> “Performance standards differ from process standards in that plant managers can take whatever actions they deem necessary to meet a performance standard.”<sup>290</sup> The HARPC program takes a performance standard approach by allowing farms and entities to design their own program.<sup>291</sup> In contrast, the produce safety standard section of FSMA is guided by process standards.<sup>292</sup> The relevant standards pertain to “growing, harvesting, sorting, packing, and storage operations” and “science-based minimum standards related to soil amendments, hygiene, packaging, temperature controls, animals in the

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286. *Id.* at 6.

287. See PROHIBITION (Florentine Films 2011) for a discussion on the challenges presented by Prohibition and federal attempts to regulate alcohol. Though Prohibition was a different era and focused on a different medium, lessons from the failed attempt can be applied to other regulatory ventures by the federal government.

288. POLLAN, OMNIVORE’S DILEMMA, *supra* note 85, at 229.

289. SALATIN, THIS AIN’T NORMAL, *supra* note 85, at 343–44.

290. OLLINGER & MOORE, *supra* note 193, at 6.

291. *See generally* 21 U.S.C. § 350g (Supp. V 2011).

292. *Id.* § 350h(a)(3), (b), (c).

growing area, and water.”<sup>293</sup> In other words, FDA provides specific methods through rulemaking and guidance to be employed in each of those steps.<sup>294</sup>

Allan Nation, editor of *The Stockman Grass Farmer*, gets to the root of the issue and explains, “None of us in alternative agriculture are opposed to government-enforced health standards. What we are opposed to are standards that dictate a high-capital solution when a lower-capital alternative is possible.”<sup>295</sup> He goes on to contend, “Devising lower-capital alternatives is our stock-in-trade, and we are really good at it.”<sup>296</sup> Wendell Berry asks, “Why have new sanitation laws always required more, and more expensive, equipment? Why have they always worked against the survival of the small producer? Is it impossible to be inexpensively healthful and clean?”<sup>297</sup> Nation and Berry recognize that most small farmers and processors are industrious and able to craft creative solutions to their specific problems. Many small farmers and processors find it easier to meet good safety practices than larger industrial farms because of their smaller scale. As Salatin sees it, food safety regulations are created under the assumption of “unimaginable pathogenicity coming from the farm” while farms like his own use production methods that do not as readily promote pathogens.<sup>298</sup> Therefore, the step-by-step and often expensive requirements constructed to guard against *all imaginable worst-case contamination scenarios* are considered unnecessary when the same objectives can be reached in an alternative manner, sometimes by simply preventing the potential for contamination in advance. The EPA already sets tolerance levels for certain pesticides and other incidental additives, a form of performance standards.<sup>299</sup> USDA governs using process standards instead of performance standards.<sup>300</sup> As an agency, USDA does not have recall authority, and therefore, violations of a performance standard, if performance standards were utilized, would go unpunished.<sup>301</sup> Under FSMA, however, FDA is granted recall authority and therefore, could theoretically utilize performance standards for produce safety to meet food safety objectives with this newly obtained en-

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293. *Id.* § 350h(a)(3)(B).

294. 78 Fed. Reg. 3504, 3534–3616 (proposed Jan. 16, 2013) (to be codified in scattered sections of 21 C.F.R.).

295. SALATIN, *THIS AIN'T NORMAL*, *supra* note 85, at ix.

296. *Id.*

297. WENDELL BERRY, *THE GIFT OF GOOD LAND* 100–01 (1981).

298. SALATIN, *THIS AIN'T NORMAL*, *supra* note 85, at 283.

299. *See, e.g.*, 40 C.F.R. §§ 141.50–.66 (2012); U.S. ENVTL. PROT. AGENCY, NATIONAL PRIMARY DRINKING WATER REGULATIONS (2009), *available at* <http://water.epa.gov/drink/contaminants/upload/mcl-2.pdf>.

300. *See* POLLAN, *OMNIVORE'S DILEMMA*, *supra* note 85, at 229.

301. *See id.*; *FSIS Food Recalls*, FOOD SAFETY & INSPECTION SERV., USDA (Oct. 14, 2011), [http://www.fsis.usda.gov/factsheets/FSIS\\_Food\\_Recalls/index.asp](http://www.fsis.usda.gov/factsheets/FSIS_Food_Recalls/index.asp).

forcement mechanism.<sup>302</sup> Performance standards must be used with caution, however, as they provided the theoretical foundation for the HACCP program discussed in Part III.A.1 and have their own weaknesses—weaknesses that can be overcome with adequate resources and proper vigilance by regulators.

#### D. Consumer Responsibility

Underlying the issue of government regulation of food is the role of consumer responsibility. Consumer responsibility for food choices is not presently a complete alternative to any and all government regulation, but a needed corollary to actions associated with a limited governmental role in food safety, and specifically, the promotion of small farms and local food markets. Telling consumers to pay more attention to the quality of the food they consume is a politically difficult message to convey, but a necessary one. Salatin makes the case by arguing, “When you have the government deciding on what can and cannot be eaten, then people become ignorant about food, ignorant about farming, eliminate their relationship with any of this because, after all, it’s got a government stamp on this so it must be fine.”<sup>303</sup> Salatin believes stepped-up government intervention in food safety oversight will lead consumers to abdicate their own responsibility and rely on the government even more for their protection.<sup>304</sup> With government’s lack of praiseworthy success in significantly reducing foodborne illness to-date, assuming FDA will be successful regulating the nation’s produce supply despite dangerously limited resources to fulfill their growing mission is naïve.<sup>305</sup> The more responsibility the government takes for our food safety with increased regulations like FSMA, the more protection consumers will expect regardless of whether the government’s inspection and enforcement actions are sufficient to make food safer and warrant increased consumer trust.<sup>306</sup> Whether from the industrial supply chain or the local food chain, no food can be guaranteed 100% safe even with comprehensive and well-funded regulations. Therefore, concerted efforts should be made to remind consumers they cannot have blind faith but must be cautious about the food they consume no matter its source.<sup>307</sup> FSMA has the opposite

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302. 21 U.S.C. § 350l (Supp. V 2011).

303. Interview by Corrigan with Salatin, *supra* note 36.

304. *See id.*

305. *See 2007 Preliminary FoodNet Data*, *supra* note 203, at 368 (indicating that although incidences of some foodborne illnesses decreased between 1996 and 2004, subsequent progress has stalled, especially with *Salmonella*).

306. Hamilton, *supra* note 40, at 18 (discussing consumer faith in our food system).

307. *See id.* (questioning whether blind faith in our food system is rewarded); *see also* HEWITT, MAKING SUPPER SAFE, *supra* note 10, at 126 (contending that eating is an act of blind faith).

effect. Neither the actions nor statements of FDA, nor the increased regulatory effect of FSMA, encourages consumers to pay more attention to their food choices.<sup>308</sup> Instead, their approach to food safety paves the way for further abdication of responsibility. In the words of Wendell Berry, “The consumer becomes the dependent not only of the manufacturer and salesman, but of the agency that enforces the law, and is at its mercy as well.”<sup>309</sup>

One can imagine that, if there was a complete absence of government regulation of food, larger food producers and processors would need spotless food safety records to gain consumer trust. The current reality, however, is that consumers do rely on the government for food safety oversight and our current system does not encourage transparency and accountability. As a result, abrupt and complete absence of government regulation could be dangerous. But for good reasons the government should hesitate to continue taking on even more responsibility when the resulting challenges in providing effective protection to consumers are so great.

## V. CONCLUSION

### *A. Does the Food Safety Modernization Act and Included Tester Amendment Serve as a Useful Safe Harbor for Small Farmers or Weak Attempt at Scale-Appropriate Farm and Food Regulations?*

With so many variables and uncertainties surrounding how FSMA will be implemented, or even when FSMA regulations will be implemented,<sup>310</sup> the question posed at the beginning of this paper is difficult to answer conclusively. While it seems clear that the inclusion of the Tester Amendment in FSMA saves *qualifying* small farmers and entities much time and expense, it still leaves those

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308. See U.S. FOOD AND DRUG ADMIN., STRATEGIC PRIORITIES 2011–2015: RESPONDING TO THE PUBLIC HEALTH CHALLENGES OF THE 21ST CENTURY 2 (2011), available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM252092.pdf> (describing FDA mission statement and goals, which are internally focused and fail to provide a strategy for promoting consumer responsibility). *But see generally* Press Release, USDA, USDA Launches ‘Know Your Farmer, Know Your Food’ Initiative to Connect Consumers with Local Producers to Create New Economic Opportunities for Communities (Sept. 15, 2009), available at <http://www.usda.gov/wps/portal/usda/usdahome?contentidonly=true&contentid=2009/09/0440.xml> (describing a federal initiative to promote consumer connections with local farmers and the food they purchase in a general effort to promote local food systems).

309. BERRY, *THE UNSETTLING OF AMERICA*, *supra* note 83, at 23.

310. Some of the initial rule proposals were not released until a year past their deadline. Helena Bottemiller, *FDA Releases Two Long-Awaited Food Safety Rules*, FOOD SAFETY NEWS (Jan. 4, 2013), <http://www.foodsafetynews.com/2013/01/fda-announces-two-long-awaited-food-safety-rules/>.

farms and food processors with the burden of proving their exemption, and the costs of losing the exemption may limit their opportunities for growth and creativity. Non-qualifying farmers are left with the burden of complying regardless how unsafe or safe are the methods they employ. Marketing and growing decisions for smaller farms will suddenly pivot around the “qualified end user,” a calculator, and percentages. These subtleties may seem insignificant, but for an occupation not known for its wide profit margins, they may spell the difference between continued viability and failure.

Perhaps it is better to question whether the Tester Amendment allows middle-sized farmers and growing small farmers the freedom to compete. Successful farms near or above the \$500,000 qualifying exemption threshold, but who practice local food marketing, will be severely disadvantaged by FSMA. They may face new regulations without sufficient resources, like the largest actors possess, to make it worth their continued investment and production. Further, successful business models might find their growth disincentivized by the threat of crossing the barrier from exempt to non-exempt. These mid-sized farms are arguably the most valuable and most adept at meeting our near-future food supply needs.<sup>311</sup>

Perhaps the most significant element of FSMA for smaller farmers and processors is the recognition that one-size regulations do not fit all. For the first time, significant concessions were made for small farmers and food processors in national food safety regulations, suggesting meaningful public support for the success of small farms and local food procurement. The distinction between small and large farms recognized by the Tester Amendment may serve as the starting template for future legislation regulating food production as legislators consider the practical effects proposed regulations will have on different sized farms.

### B. *Moving Forward*

In 2009, the CDC reported, “Despite numerous activities aimed at preventing foodborne human infections . . . progress toward the national health objectives has plateaued, suggesting that fundamental problems with bacterial and parasitic contamination are not being resolved.”<sup>312</sup> Reports like this aided in generating the political enthusiasm for passing sweeping reform through FSMA. Nevertheless, skeptics argue these new regulations may not be the cure-all regulators and consumers are expecting or hoping for. FSMA is hailed as being a

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311. See generally KIRSCHENMANN, *supra* note 165, at 2.

312. 2008 *Preliminary FoodNet Data*, *supra* note 8, at 336.

preventive scheme instead of a reactionary scheme.<sup>313</sup> While FSMA attempts to implement practices that reduce the risk of contamination of produce through sanitation and careful handling, it disappointingly does nothing to eradicate the root of the contamination problem—the specific farming practices that promote the survival, evolution, and replication of toxic bacteria—and prevent the harmful pathogens from developing in the first place.<sup>314</sup> As long as this critical flaw remains, efforts to keep food safe are likely to continually fall short of the public's growing expectations. FSMA is effectively treating the symptoms, not the disease,<sup>315</sup> prompting some to point out, “[t]he solution to the food safety problem is to produce safe food.”<sup>316</sup>

It is a chorus long sung by many in the field of agriculture, but this time the calls for fewer and more sensitive regulations are coming not from industrial agriculture but from a different choir—small farmers and processors. Moving forward, all new regulations must be sensitive to the needs of the diverse spectrum of farms and processing facilities. I argue federal schemes, like FSMA, are inherently incapable of meeting this level of sensitivity. Additionally, existing regulations, including FSMA once its implications are better understood or demonstrated, must be reexamined and altered to allow local food production and sales to meet the growing demand and provide local food security apart from the more vulnerable industrial system. States like Illinois, Minnesota, Kentucky, and Oregon, among others, have taken steps to enact or consider legislation that would loosen restrictions on qualifying small farmers and processors—measures often referred to as “cottage food laws.”<sup>317</sup> For example, Illinois no longer requires commercial kitchens for all commercial food production if the producer meets the definition of a “cottage food operation.”<sup>318</sup> Many of the laws currently

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313. JOHNSON, FSMA, *supra* note 30, at 7.

314. See Ctrs. for Disease Control & Prevention, *Preliminary FoodNet Data on the Incidence of Foodborne Illnesses—Selected Sites, United States, 2001*, 51 MORBIDITY & MORTALITY WEEKLY REPORT 325, 328 (2002), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5115a3.htm> (suggesting further efforts to curb foodborne illness focus on pathogen vectors, such as livestock and poultry); see also HEWITT, MAKING SUPPER SAFE, *supra* note 10, at 253 (suggesting FSMA will not “heal the structural deficiencies” in our food system).

315. HEWITT, MAKING SUPPER SAFE, *supra* note 10, at 31 (suggesting “foodborne illness isn’t the disease,” but only “a symptom of a larger, more systemic” problem).

316. Rodney Leonard, *Food Safety Mismanagement Puts Consumer Health at Risk*, 29 NUTRITION WEEK, Apr. 16, 1999, at 5 (emphasis added).

317. See, e.g., 410 ILL. COMP. STAT. ANN. 615/4 (LexisNexis 2012); KY. REV. STAT. ANN. § 217.137 (LexisNexis 2007); MINN. STAT. ANN. § 28A.15 (West 2010); OR. REV. STAT. § 616.683 (2012); see also James Andrews, *Relaxing the Rules for Small, Local Food Sellers*, FOOD SAFETY NEWS (Mar. 16, 2011), <http://www.foodsafetynews.com/2011/03/loosening-the-rules-for-small-local-food-sellers/>.

318. 410 ILL. COMP. STAT. ANN. 615/4.

on the books arose out of a need to meet the challenges presented by industrial agricultural models that have become prevalent over the past six or seven decades. As public support for freedom of food choice gains momentum, we now face the challenge of adapting those regulations to allow room for more traditional forms of agriculture and food production on a localized scale. The most notable example is the processing and sale of cut meat, which currently requires expensive facilities and access to a government inspector. Many farmers recognize and desire to address the local demand for meat products, but the cost of compliance is too high.<sup>319</sup> A re-examination of all food safety regulations could serve to create an environment where small farms and processors are given a fair chance at success and food safety principles are still respected by differentiating “what actually promotes [food] safety versus what is just unnecessary regulation.”<sup>320</sup>

The past century witnessed a dramatic decrease in the number of U.S. farms, but the 2007 census of agriculture registered a four percent increase in the number of farms since the 2002 census, reversing a multi-decade-old trend of decline.<sup>321</sup> This suggests that despite the present regulatory challenges, many small farms have creatively found ways to survive and even increase in number. Even so, un-scaled and sloppy regulations remain an impediment to a truly viable and widespread local food system. Regulations like FSMA, even with exemptions for specified small farms and food processors, do more to harm than help the success of local food systems; systems that may in fact hold the key to a more successful food safety record—one we can all live with.

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319. Katie Zezima, *Push to Eat Local Food Is Hampered by Shortage*, N.Y. TIMES, Mar. 27, 2010, <http://www.nytimes.com/2010/03/28/us/28slaughter.html>; see also FOOD & WATER WATCH, *supra* note 112, at 38 (analyzing USDA estimates of the costs of compliance).

320. Andrews, *supra* note 317.

321. NAT'L AGRIC. STATISTICS SERV., USDA, AC-07-A-51, 2007 CENSUS OF AGRICULTURE: UNITED STATES SUMMARY AND STATE DATA 7 tbl.1 (2009), available at [http://www.agcensus.usda.gov/Publications/2007/Full\\_Report/usv1.pdf](http://www.agcensus.usda.gov/Publications/2007/Full_Report/usv1.pdf).